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MMJ

January 1985

Maryland Medical Journal

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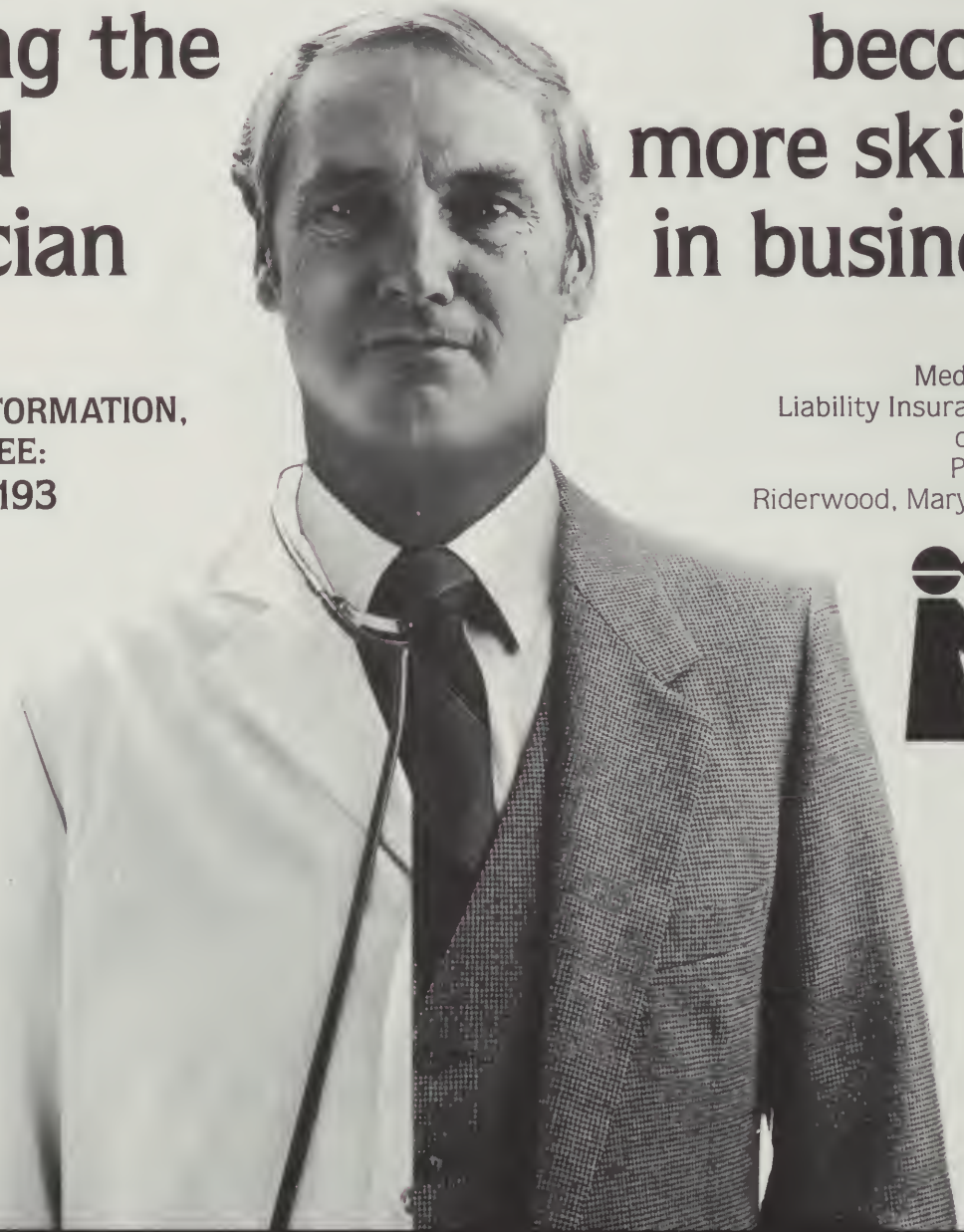
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January 1985

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MISCELLANY

Executive Director's Newsletter . . . 17
Physicians' Placement Service . . . 76
Change of Address Form . . . 90
Doctors Take Note . . . 95
Classified Ads . . . 99
Advertisers' Index . . . 101

ARTICLES

Cancer: A Preventable Disease—Albert M. Antlitz MD, Janet L. Campbell MS, and Carmine M. Valente PhD . . . 39

Cancer as a Preventable Disease—Vincent T. DeVita, Jr., MD . . . 41

Diet and Cancer Prevention—Peter Greenwald MD . . . 44

Using Four Simple Steps, Physicians Do Influence Smoking Behavior—Janet L. Campbell MS, Carmine M. Valente PhD, David Levine ScD, and Albert M. Antlitz MD . . . 50

Estrogens and Endometrial Cancer—W.B. Schlaff MD and N.B. Rosenshein MD . . . 57

Public Perception of Cancer Risk and Prevention: Implications for Physicians—Joy Wilson MPH, Rose Mary Romano MA, and Judith Stein MA . . . 63

Cancer Risk Reduction: A Focus on Physicians—Carmine M. Valente PhD and Janet L. Campbell MS . . . 67

Cancer Statistics in Maryland and the United States—John L. Young, Jr., DrPH and John W. Horm MS . . . 72

Economic Evaluation of the Benefits of Cancer Prevention and Health Promotion Programs—Andrew M. Tager AB and Edward J. Sondik PhD . . . 77

Resources: Cancer Prevention—Donna S. Cox MEd and Kay C. VanSant . . . 83

DEPARTMENTS

Annual Meeting Announcements . . . 6

Your Medical Faculty at Work . . . 11

Disease Control and Epidemiology Newsletter . . . 31

Articles in this issue reflect the current understanding regarding cancer risk reduction, its importance, and the role physicians can play in cancer prevention. Guest editors are Albert M. Antlitz MD, Carmine M. Valente PhD, and Janet Campbell MS.

Because dedicated issues require more pages, our editorial policy is to exclude all departments from the *Journal*.

Cover illustration by the National Cancer Institute.

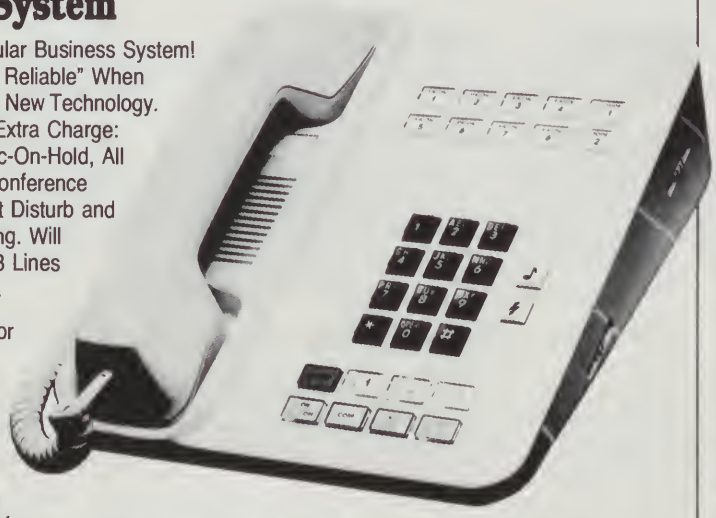
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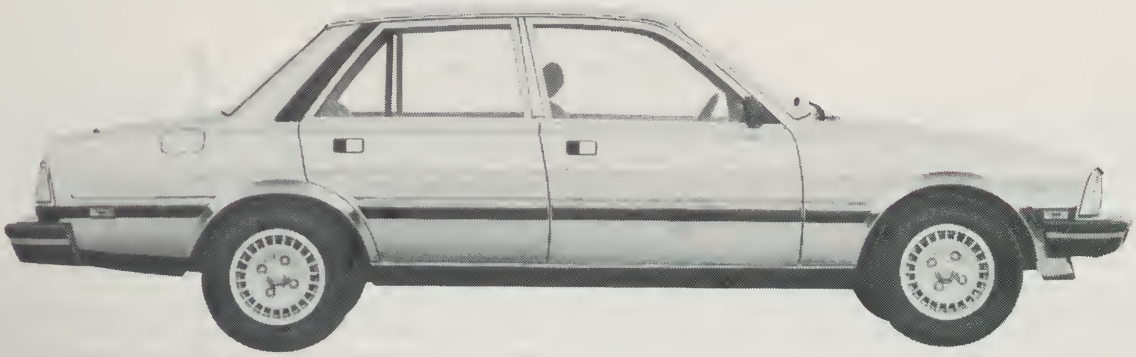
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Medical and Chirurgical Faculty of the State of Maryland

187th ANNUAL MEETING

Thursday–Saturday, April 25–27, 1985

HUNT VALLEY INN

THURSDAY, APRIL 25, 1985

8:30 a.m.
COUNCIL

9:30 a.m.
HOUSE OF DELEGATES
All members are invited to attend.

8:45 a.m.
LEGISLATION POLICY WITH REGARD TO PHYSICIAN ASSISTANTS, **F. Lynn May,** Arlington, VA and **Curtis Decker,** Annapolis

PRESENT UTILIZATION OF PHYSICIAN ASSISTANTS
Education and Training, Robert Solomon PA-C, Baltimore; **Surgical Physician Assistants, Jeffrey Stark PA-C,** Baltimore; **Physician Assistants Used as Medical Housestaff, Bernard Tabatznik MD,** Baltimore; **Emergency Room Physician Assistants, Wayne S. Barry MD,** Baltimore;

FUTURE ROLE OF PHYSICIAN ASSISTANTS IN THE HEALTH CARE DELIVERY SYSTEM, **James Cawley PA,** Washington DC, **Karl Katterjohn PA-C,** Baltimore and **Gretchen Shafft,** Baltimore, Maryland Academy of Physician Assistants

12:15 p.m.
PRAYER LUNCHEON
Pastoral Care: Profession, Plebeian Career, or Placebo? The Reverend Grady F. W. Barbour, Linthicum, Committee on Medicine and Religion/Med-Chi

1:00 p.m.
The Field Liaison for the American College of Surgeons Meeting—All Liaison Fellows and Associate Fellows are Invited to Attend

2:00 p.m.
DEALING WITH THE SOMATIZING PATIENT
Somatization: Diagnosis and Management, Charles V. Ford MD, Nashville, TN; **Somatization: Impact Upon the Patient's Family, Lee Randol Barker MD,** Baltimore, The Maryland Psychiatric Society, Inc.

Emotional Development in the First Eighteen Months: Principles of Intervention and Clinical Diagnosis in Infancy, Serena Wieder PhD, Silver Spring, Maryland Chapter, American Academy of Pediatrics/Infant, Child & Adolescent Health Subcommittee/Med-Chi

Introductory Remarks, Paul Bormel MD, Baltimore; **Joseph S. McLaughlin MD,** Baltimore—**Moderator; Pancreatic Transplantation, Frederick R. Bentley MD,** Baltimore; **Breast Reconstruction After Mastectomy—Immediate versus Delayed, Nelson H. Goldberg MD,** Baltimore; **Application of the Laser to Surgery, William C. Gray MD,** Baltimore, Maryland Chapter, American College of Surgeons

Aneurysms, Harold P. Adams, Jr., MD, American Heart Association, Maryland Affiliate/Stroke Working Group

The Role of Food Hypersensitivity and Atopic Dermatitis, Hugh A. Sampson MD, Durham, NC, Maryland Asthma and Allergy Society

Endoscopy Update 1985, David Fleischer MD, Washington DC, Maryland Society of Gastrointestinal Endoscopy

Keeping the Elderly Functional and Fit, Franz U. Steinberg MD, St. Louis, MO, Maryland Society of Physical Medicine and Rehabilitation

EFFECTIVE COMMUNICATION CAN REDUCE YOUR RISKS OF MEDICAL LIABILITY, **Marlyn D. Boyd PhD,** Columbia, SC and **Allen Douma MD,** Washington DC, Center for Health Education

4:00 p.m.
PLENARY SESSION
THE CHALLENGE OF CHANGE, **Paul M. Ellwood, Jr. MD,** Excelsior, MN

FRIDAY, APRIL 26, 1985

8:45 a.m.
BREAKFAST AND LEARN

FUTURE PERSPECTIVES OF OTOLARYNGOLOGY—HEAD AND NECK SURGERY
Topic and Speakers to be Announced, Maryland Society of Otolaryngology—Head and Neck Surgery

HELPING YOUR PATIENTS CONTROL THEIR BLOOD LIPIDS
Introduction, Frank Franklin MD, Baltimore; **When and How to Evaluate a Patient's Lipids, Thomas Pearson MD,** Baltimore; **What Can be Learned from a Family History & Apoprotein Measurements, Peter Kwiterovich MD,** Baltimore; **What Diet Should I Recommend? Frank Franklin MD;** Questions and Answers

Break

Introduction, Diane Becker RN, Baltimore; **How to Help Patients Change Habits and Lose Weight, Kelly Bronwell MD,** Philadelphia, PA; **How to Start and Maintain Patients in Exercise Programs, Andrew Goldberg MD,** Baltimore; **How to Help Patients to Stay on Diets in Everyday Life, Virginia Hartmuller MD,** Baltimore; **When and How to Begin Lipid Lowering Medications, Simeon Margolis MD,** Baltimore, American Heart Association, Maryland Affiliate, Inc.

Respiratory Failure and Chronic Obstructive Pulmonary Disease, Peter Terry MD, Maryland Thoracic Society

3rd Annual Meeting of the Directors of Medical Education, Continuing Medical Education Review Committee/Med-Chi

Topic to be Announced, William R. Irby MD, Richmond, VA, Maryland Society for the Rheumatic Diseases/Pfizer Laboratories

10:45 a.m.
The Challenge of Change: Governmental and Socioeconomic Changes in the Health Field, Peyton E. Weary MD, Charlottesville, VA, Maryland Dermatologic Society

Tissue Expanders, John B. McCraw MD, Norfolk, VA, The John Staige Davis Society of Plastic Surgeons of Maryland

THE PHYSICIAN, HIS PATIENT, AND THE WORKPLACE
Post-Coronary By-Pass Patients: Their Ability to Return to Work, Phillip Achuff MD, Baltimore; **Asbestosis: How Serious a Problem is it?, Paul Wheeler MD,** Baltimore; **Prescription Medicines: How They Affect the Ability to Work, Michael Spodak MD,** Baltimore, Maryland Occupational Medical Association/Occupational Health Committee/Med-Chi

Ethical Issues in the Management of Chronic Lung Disease, Joseph Miller MD, Baltimore, Maryland Lung Association of Maryland

Topic to be Announced, Kenneth H. Williams MD, Ft. Washington, PA, Committee on Physician Rehabilitation/Committee on Alcoholism/Med-Chi

12:15 p.m.
LUNCH AND LEARN

2:00 p.m.
UPDATE ON HIGH BLOOD PRESSURE: 1985
New Drugs and Old Favorites: What to Choose, Ray W. Gifford Jr. MD, Cleveland, OH; **The Five-Hour Office Blood Pressure Check: An Alternative to Hospitalization, Lee Randol Barker MD,** Baltimore; **The New Division of Hypertension: The University of Maryland School of Medicine, Elijah Saunders MD,** Baltimore; **The Role of Calcium, Sodium, and Other Nutrients in Blood Pressure Regulation, Michael J. Horan MD,** Bethesda; **The Systolic Hypertension in the Elderly Program (SHEP), Roger Sherwin MD,** Baltimore; **JNC III: Changes in HBP Referral and Guidelines, Donald O. Fedder DrPH,** Baltimore, Maryland High Blood Pressure Commission

RESOLVING AND AVOIDING MEDICAL STAFF CONFLICTS IN MULTI-SPECIALTY HOSPITALS: A MARKETING APPROACH, **Andrew P. Morley MD,** Decatur, GA and **Ellen J. Belzer,** Kansas City, MO, Maryland Academy of Family Physicians

SPOUSE ABUSE—**Honorable Martha Wyatt,** Annapolis—**Moderator**
Remedies Available to Battered Spouses, Honorable John J. Bishop Jr., Towson; **Legal Resources Available to Battered Spouses, L. Tracy Brown, Esquire,** Baltimore; **Why Does She Stay? Harriet Douglas LCSW,** Annapolis; **Medical Aspects of Domestic Violence, Bruce L. Regan MD,** Baltimore; **Clinical Research on Consequences of Criminal Sanctions for Domestic Violence: Implications for Medical Practice and Ethics, Lawrence W. Sherman PhD,** College Park, Office of the Attorney General for the State of Maryland/Med-Chi

DEMONSTRATION OF A MEDICOLEGAL TRIAL INVOLVING TRAUMATIC CHRONIC PAIN SYNDROME
Elliott Fishel MD, Medical Moderator—**H. Albert Korn, Esquire,** Legal Moderator

Physicians
Don M. Long MD, Baltimore, **Paul McAffee MD,** Baltimore, **Godfrey Pearlson MD,** Baltimore, **David Conblath MD,** Baltimore

Judges
The Honorable Robert L. Karwacki, Annapolis, **The Honorable John P. Corderman,** Washington County, **The Honorable John F. McAuliffe,** Montgomery County

Attorneys
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Critique
Elliott Fishel MD
William G. Speed III MD
Medicolegal Committee/Med-Chi

Changing Gears to Meet the Challenge of the Geriatric Imperative, William R. Hazzard MD, Baltimore Long Term Care and Geriatrics Committee/Med-Chi

Challenges In Choosing the Best Treatment for the Emotionally Disturbed Adolescent, Jay LeBow MD, Ellicott City, Taylor Manor Hospital

Quality, Technology and Malpractice: Are We Victims of Our Own Devices? William F. Jessee MD, Chapel Hill, NC, Medical Mutual Liability Insurance Society of Maryland

THE HORIZONS OF CHANGE IN ORTHOPEDICS
Topics and Speakers to be Announced, Maryland Orthopaedic Society

4:00 p.m.
Smoking—the #1 Health Problem, Edward N. Brandt Jr. MD, Baltimore, Committee on Preventive Medicine and Public Health/Med-Chi

Acute Post-Operative Hypertension, Leigh Thompson MD, Indianapolis, IN, Maryland-DC Society of Anesthesiologists

APPROACH TO SWALLOWING PROBLEMS: A PANEL DISCUSSION
Neurology, David W. Bucholz MD, Baltimore; **Radiology, Martin W. Donner MD,** Baltimore; **Otolaryngology, Bernard R. Marsh MD,** Baltimore; **Gastroenterology, William J. Ravich MD,** The Johns Hopkins Swallowing Clinic

Bone Imaging in the Study of Pleasure and Pain, Lawrence E. Holder MD, Baltimore, Maryland Society of Nuclear Medicine

Ophthalmology for the Non-Ophthalmologist, Earl D. Kidwell MD, Baltimore, Maryland Society of Eye Physicians and Surgeons

SATURDAY, APRIL 27, 1985

8:30 a.m.
Ovarian Echos, Peter L. Cooperberg MD, Vancouver, Canada; **Fetal Intervention, David Graham MD,** Rochester, NY, Maryland Radiological Society/ Obstetrical and Gynecological Society of Maryland

8:45 a.m.
Changing Concepts in Pathology—With Particular Emphasis on Urological Pathology, Fathollah K. Mostofi MD, Washington DC, Maryland Society of Pathologists

PRO: How Will it Affect Your Patients, Speaker to be Announced, Public Relations Committee/Med-Chi

10:45 a.m.
PLENARY SESSION
PHYSICIANS AND THEIR FAMILIES
Commonly Encountered Problems in the Families of Physicians, William L. Webb Jr. MD, Baltimore

Panel:
J. D. Drinkard MD, Moderator
Sexual Problems, Emile A. Bendit MD, Baltimore
Issues of Substance Abuse, Sheldon I. Miller MD, Baltimore
Depression and Anxiety, Dean Schuyler MD, Baltimore Sheppard and Enoch Pratt Hospital

12:30 p.m.
MMPAC LUNCHEON
Topic to be Announced, The Honorable Larry Young, Chairman House Environmental Matters Committee, Maryland General Assembly

2:00 p.m.
House of Delegates

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5. Entries may be mailed or brought to the Faculty Office, 1211 Cathedral Street, Baltimore, Maryland 21201 by the close of the business day on March 27, 1985.
6. Entries MUST be matted or dry mounted. No framed photographs will be accepted.
7. Photographs entered in the contest will be on display at the Annual Meeting in April 1985.
8. Winners will be announced at the Annual Meeting of the Medical and Chirurgical Faculty, April 25 thru 27, 1985.
9. Photographs will NOT be mailed back. Photographs may be claimed at the exhibit area at the close of the Annual Meeting on Saturday, April 27 at noon or at the Faculty Building thereafter.
10. The Faculty does not guarantee against loss or damage of any kind to the photographs submitted to the contest.
11. Prizes will be awarded to the FIRST and SECOND place winners. Additional information about the prizes will be published in the JOURNAL.

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You conclude that your patient should spend some time in a psychiatric hospital. More than a little time, given the nature of this particular problem.

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Contact Dr. David Waltos, Admissions Officer, Sheppard and Enoch Pratt Hospital, P.O. Box 6815, Baltimore, Maryland 21204. (301) 823-8200.



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Your Medical Faculty at Work

In its meeting on Thursday, November 15, 1984, Council made some major policy decisions dealing with public interest matters.

Approval was given to the following resolution dealing with child abuse:

Whereas, Physical and sexual abuse of children is a continuing problem;

Whereas, It behooves the medical profession to become more acquainted with physical and emotional signs of the abused child;

Whereas, It is imperative that physicians become more knowledgeable and take a leading role in the discovery and reporting of child abuse, and in testifying in child abuse cases; therefore, be it

Resolved, That the Council of the Medical and Chirurgical Faculty reaffirms the role of the physician in the discovery, reporting and testifying in cases of child abuse; and be it further

Resolved, That the Faculty develop programs to educate the physician in dealing with all aspects of the problems of child abuse.

Because of concern over a recent U.S. Supreme Court decision permitting therapeutic abortions to be performed on an outpatient basis, the Subcommittee on Maternal Welfare requested approval of additional Guidelines for the Performance of Therapeutic Abortions. They establish stricter standards for those facilities performing second trimester abortions. In addition, Council authorized the Subcommittee to charge for abortion facility inspections and to carry them out on a biennial basis. This action will ensure that such initially approved facilities will continue to meet the minimum standards promulgated by the Faculty in 1973.

Council recommended to the House of Delegates, for consideration at the 1985 Annual Meeting, an increase from $5 to $10 for the Physician Rehabilitation Committee. This increase will enable part-time employment of an individual to assist the Committee in its "confrontations," and also in providing support services to impaired physicians and family members.

The Professional Ethics Committee obtained approval of the following statement on abandoment:

Revised Statement on Abandonment

When a physician is away from his practice or otherwise unavailable, it is his responsibility to make suitable arrangements with another physician or group of physicians. This information must be readily available to his patients. Failure to make suitable arrangements could be construed as abandonment. For example, a recorded message on a physician's telephone simply advising his patients to go to the 'nearest emergency room' is unsuitable and could be construed as abandonment.

This material will be included in the soon-to-be published "Compendium of Laws, Regulations, Opinions and Policies Governing the Practice of Medicine in Maryland."

In other matters, Council members heard an update on the activities of the Governor's Task Force on Health Care Costs; approved $400 to the Student Component for its activities in connection with the annual Residency Planning Seminar; renewed the WBJC-FM Radio talk show commitment; approved recommendation to the House of Delegates for an Emeritus Member; as well as appointments to the Medical Advisory Board, Motor Vehicle Administration.

Following the conclusion of the business, a presentation of resolutions was made to Mrs. Patricia McHold, daughter of the late Russell S. Fisher MD. In making the presentations, the President said, "I have known and admired your father for 25 years. It is a very special privilege to present you with these resolutions."

JOHN SARGEANT
Executive Director

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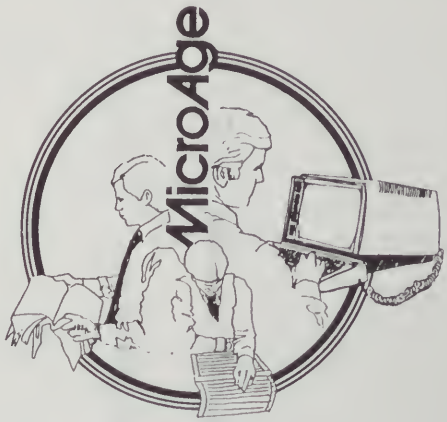
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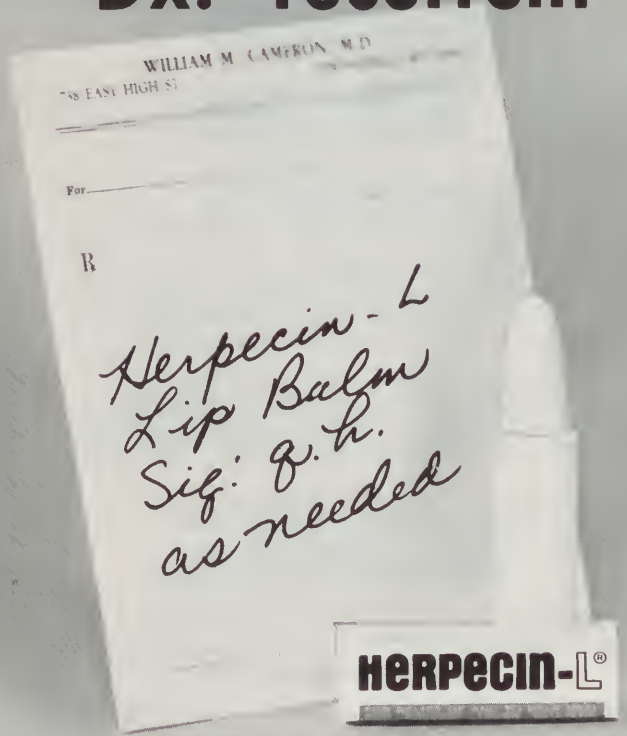
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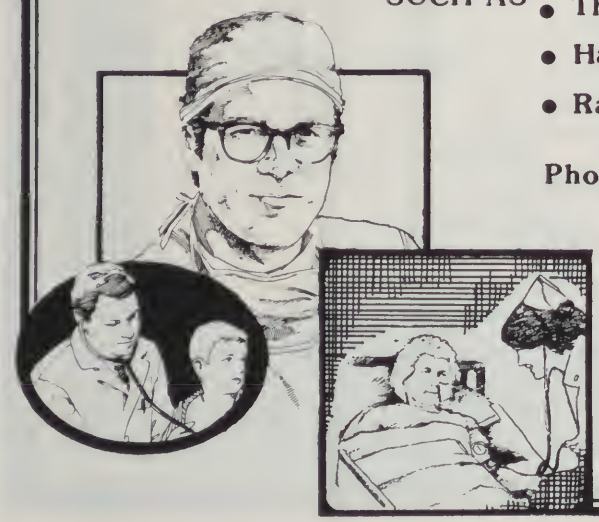
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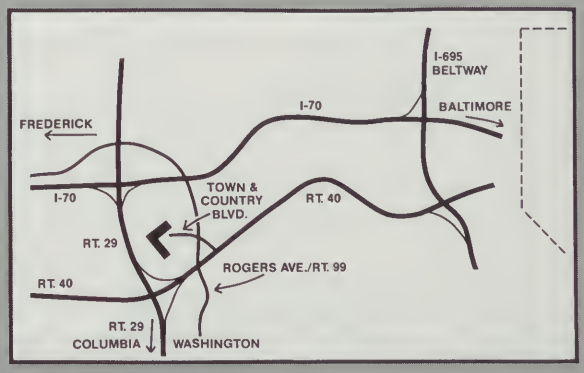
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Executive Director's Newsletter

January 1985

LEGISLATURE CONVENES

The General Assembly of Maryland convenes for its 1985 session on Wednesday, January 9, adjourning 90 days later on Monday, April 8, at midnight.

Cited by some as the Year of the Doctor, there are many thorny issues scheduled to come before the session, not the least of which is one that would place physicians' offices under the Certificate of Need program for capital expenditures of over $600,000. Physicians are presently exempt from these requirements.

Another prickly point is placing so-called "monopoly" physicians under the jurisdiction of the Health Services Cost Review Commission. No draft bill has been seen at the time of this writing, but the definition will be one that easily could encompass all physicians.

Use of topical diagnostic agents by Optometrists will surely be an issue, as will the banning of employment of Physical Therapists by physicians. A Truth-in-Treatment bill is also anticipated. This would require physicians to estimate the total cost of providing care, to quote this in writing to the patient and to not vary beyond a set percentage in billing.

These, plus many other issues that will be scheduled for hearings, promise a rather hectic time in Annapolis.

We hope we can call on all members, as the need arises, to assist us in making contact with their local legislators.

MEDICARE PAMPHLET

The AMA has published a pamphlet for use by physicians who have elected not to take Medicare assignments. An explanation of why the individual physician did not elect to take this route gives the patient a better understanding of the physician's reasoning. All members were advised of this through a special mailing from their local or state medical association. Copies are available at no charge by contacting the Faculty office at 1-800-492-1056 or 539-0872.

OPINION RESEARCH ACTIVITY

The National Opinion Research Center will be conducting a telephone survey of over 5,000 physicians with respect to their 1983 Physicians' Practice Costs and Incomes. The results of this survey will update knowledge of physicians' practice economics.

This is being carried out at the request of the Health Care Financing Administration and a high response to the survey is in the mutual interest of practicing physicians and that agency.

REVISED COMPENDIUM AVAILABLE

The newly revised Compendium of Laws, Regulations, Opinions and Policies Governing the Practice of Medicine in Maryland is now available at no charge to Med-Chi members and at a charge of $26 to nonmembers. This publication summarizes Maryland laws affecting the physician in his or her everyday practice and also sets forth the current ethical opinions and policies of the Faculty. Many of the older ethical opinions have undergone major revisions or have been deleted entirely to reflect the significant changes that have taken place in medicine and to comply with antitrust laws. I strongly urge each physician to request a copy of this useful publication. Please use the convenient post card opposite this page when ordering.

PREPRINTED RXS

Pharmacists are expressing concern to the Faculty over some physicians use of preprinted Rx blanks. Some of these are for Schedule II drugs. Use of such blanks fosters the potential for forgery.

Physicians are urged to decline use of preprinted Rxs and to keep prescription pads out of sight.

RESOLUTIONS DEADLINE

The deadline date for receipt of resolutions for consideration at the 1985 annual session of the House of Delegates is

FRIDAY, MARCH 1, 1985

Resolutions must be sponsored by a member or component society of the Faculty, the Council, or committees of the Faculty. A resolution introduced by an individual member must have the endorsement of either one-third of the membership of his component society or 30 members of his component society, whichever is smaller.

1985-86 COMMITTEE APPOINTMENTS

Committee appointment requests have been mailed to all Faculty members. Completion of the card, indicating your choice of committee, does not necessarily mean you will be appointed to such a committee, however.

Frequently, committees have a limited number of openings for new members, primarily because of the rotation system of replacement. The incoming President and Committee Chairmen have the opportunity to review the request cards and to select appointees based on geographic representation, as well as specialty. This information also is used throughout the year by the President and Council Chairman in filling requests for appointments to special committees.

John Sargeant
Executive Director

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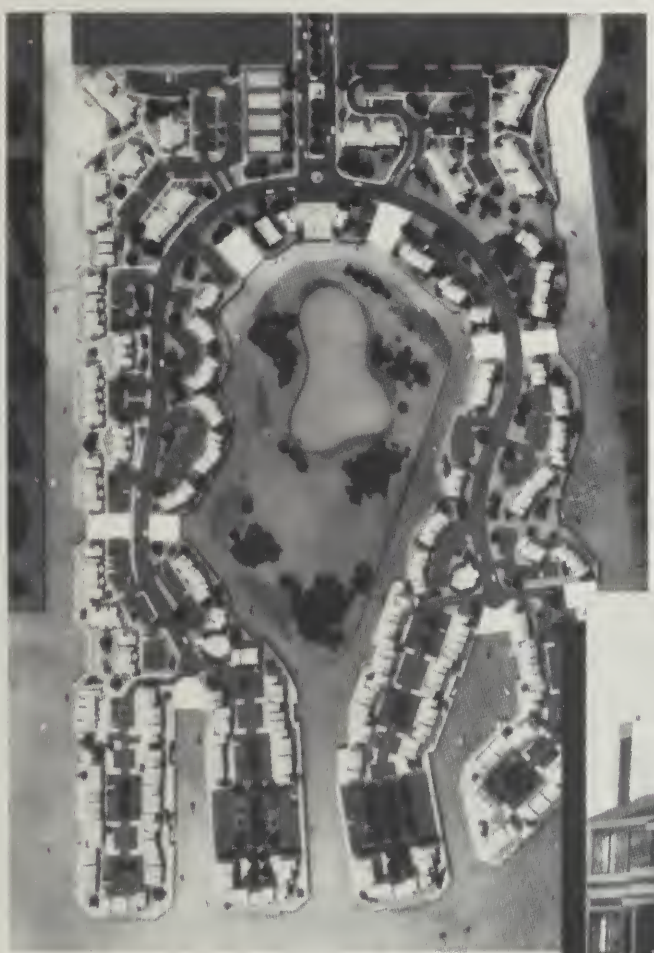
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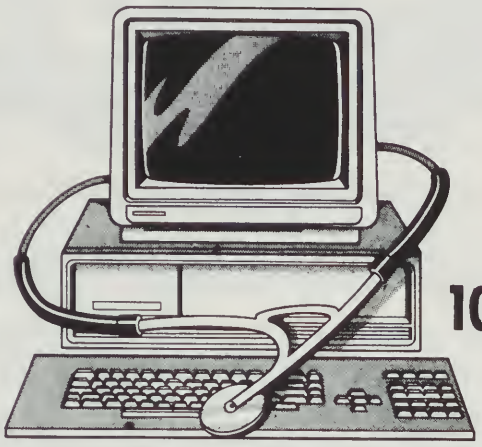
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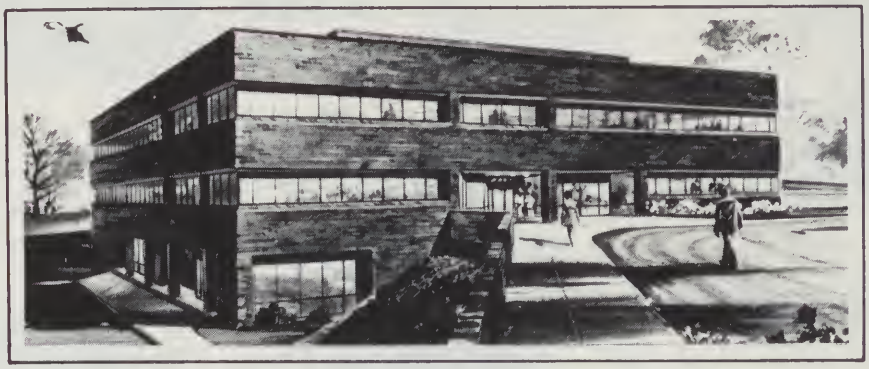
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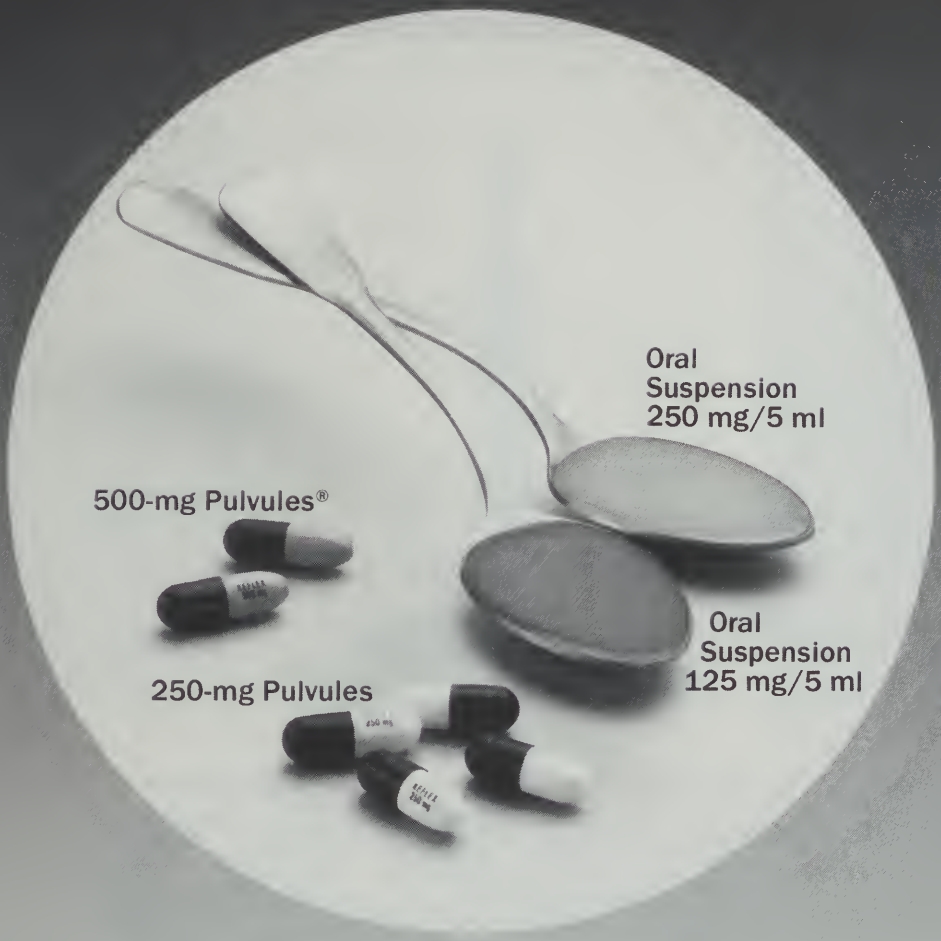
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Adele Wilzack, R.N., M.S.
Secretary of Health and Mental Hygiene
Eric M. Fine, M.D., M.P.H.
Director, Preventive Medicine Administration
Ebenezer Israel, M.D., M.P.H.
Chief, Office of Disease Control & Epidemiology

Office of Disease Control and Epidemiology Newsletter
PREVENTIVE MEDICINE ADMINISTRATION
MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE

201 W. PRESTON STREET/BALTIMORE, MARYLAND 21201/(301) 383-2644

JANUARY 1985

SAFETY OF HEPATITIS B VACCINE

Recent studies have provided important additional assurances concerning the safety of hepatitis B (HB) vaccine. The vaccine currently licensed in the United States is produced from pooled plasma of hepatitis B surface antigen-positive individuals, some of whom are also in high-risk groups for acquired immunodeficiency syndrome (AIDS). Concern has been expressed that the etiologic agent of AIDS might be present in the vaccine and survive the inactivation steps used in the manufacturing procedure. The concerns persisted, despite the fact that these steps were reportedly able to inactivate representative members of all known virus groups. The recent identification of a retrovirus as the etiologic agent of AIDS has allowed workers to (1) directly test the inactivation of the AIDS virus by the inactivation steps used in the vaccine manufacturing procedure; (2) look for the AIDS virus' nucleic acid sequences in the vaccine; and (3) look for serologic markers of infection from the AIDS virus in vaccine recipients. Concurrently, monitoring of AIDS patients and high-risk groups has continued in order to look for any epidemiologic evidence of an association between HB vaccine and AIDS.

The effect of the HB vaccine inactivation process on the AIDS virus and two other human retroviruses (HTLV-I and HTLV-II) was studied. Three separate inactivation steps are used in the manufacture of the U.S.-licensed HB vaccine: (1) 1 µg/ml pepsin, pH 2, 37 C (98.6 F), 18 hours; (2) 8 molar urea, 37 C (98.6 F), 4 hours; and (3) 0.01% formaldehyde, 37 C (98.6 F), 72 hours. In separate studies conducted between CDC and the vaccine manufacturer Merck, Sharp & Dohme (MSD), and between State University of New York (SUNY) Upstate Medical Center and MSD, cell culture supernatant fluid containing the AIDS virus and cultured cells containing HTLV-I, HTLV-II, and the AIDS virus were transported to MSD and individually exposed to the three inactivation steps. The materials were then returned to CDC and SUNY for detection of residual viral infectivity. Virus infectivity was assayed by adding the treated material to cultured

lymphocytes and periodically monitoring these for signs of viral replication (reverse transcriptase activity and virus antigen expression) and in the case of HTLV-I and HTLV-II, transformation. No residual virus was detected in material treated with formalin or urea, while material treated with pepsin at pH 2 did have residual virus present. Heat, an inactivation step used in vaccines manufactured outside the United States, has also been shown to inactivate the AIDS virus.

The second approach, which attempted to detect AIDS virus-related nucleic acid sequences using dot blot hybridization analysis of the vaccine with an AIDS virus deoxyribonucleic acid (DNA) probe, was done at MSD using as a positive control infected cellular (ribonucleic acid) RNA preparations provided by CDC. The vaccine contained no detectable AIDS virus-related sequences at a sensitivity of less than one picogram of DNA per 20-µg dose of vaccine.

The third approach attempted to detect seroconversion to AIDS virus antibodies in paired sera of HB vaccine recipients. Paired sera were examined at CDC using a highly sensitive and specific ELISA assay for the AIDS virus. No seroconversions were detected in 19 individuals who had received vaccine manufactured from plasma pools that contained plasma of homosexual men. Previous workers have reported that sera of HB vaccine recipients did not show helper-T/supressor--T ratio inversion, a finding common in AIDS patients.

Epidemiologic approaches to detect an association between HB vaccine and AIDS have included analysis of data on AIDS cases reported to CDC concerning their receipt of HB vaccine and monitoring rates of AIDS in groups of homosexually active men who did or did not receive HB vaccine in the vaccine trials conducted by CDC in Denver, Colorado, and San Francisco, California. To date, 68 AIDS cases have been reported among approximately 700,000 U.S. HB vaccine recipients; 65 have occurred among persons with known AIDS risk factors, while risk factors for the remaining three are under investigation. In addition, the rate of AIDS for HB vaccine recipients in CDC vaccine trials among homosexually active men in Denver and San Francisco does not differ from that for men screened for possible participation in the trials but who received no HB vaccine because they were found immune to HB.

Editorial Note: The Immunization Practices Advisory Committee (ACIP) has recommended preexposure HB vaccination for susceptible members of the following groups in the United States: health-care workers (medical, dental, laboratory and support groups) judged to have significant exposure to blood or blood products; clients and selected staff of institutions for the mentally-retarded; hemodialysis patients; homosexually active males; users of illicit, injectable drugs; recipients of certain blood products (patients with clotting factor disorders); and household and sexual contacts of HB virus (HBV) carriers. In addition, vaccine may be warranted for classroom contacts of deinstitutionalized mentally-retarded HBV carriers; special high-risk populations (Alaskan Eskimos and immigrants and refugees from areas with highly endemic disease); inmates of long-term

correctional facilities; and some U.S. citizens living or traveling abroad. The ACIP has also recommended screening all pregnant women belonging to high-risk groups for HB and treating their newborn infants with hepatitis B immune globulin and HB vaccine.

HB vaccine acceptance in the United States has been seriously hindered by the fear of possible AIDS transmission from the vaccine. The recent identification of AIDS' etiologic agent has made possible direct laboratory measurement of virus inactivation, nucleic acid presence, and serologic evidence of infection. These studies were unable to detect the AIDS virus' viral protein or nucleic acid in the purified vaccine product and clearly indicate that if virus were present, it would be killed by the manufacturing procedures. In addition, epidemiologic monitoring of AIDS cases and high-risk groups confirms the lack of AIDS transmission by HB vaccine. This information should remove a major impediment to vaccine use.

DIPHTHERIA-TETANUS-PERTUSSIS VACCINE SHORTAGE--UNITED STATES

In the past 6 months, major changes have occurred in the pattern of manufacture and distribution of diphtheria-tetanus-pertussis* (DTP) vaccine in the United States. Now, two of the three U.S. commercial manufacturers (Wyeth and Connaught, Inc.) have stopped distribution of their products. Thus, only one manufacturer (Lederle) now markets DTP vaccine in the United States. Lederle has been increasing its production and expanding its facilities to meet current needs. Careful monitoring of supplies and production schedules previously indicated that national supplies would be adequate. However, some recent lots of Lederle DTP vaccine have failed to meet the manufacturers' requirements for release. Production and testing of this three-component vaccine is complex and requires several months. No new vaccine lots may be available until sometime in February 1985. Comparison of available stocks and the quantity of DTP vaccine now being distributed with the usual national utilization of DTP vaccine indicates that, if current use patterns continue, beginning in January 1985, supplies of DTP vaccine will be very limited, and some areas may be without DTP vaccine. This situation may continue through most of 1985.

To minimize the health impact of this shortage, two major options exist--to reduce the amount of vaccine given in a particular dose and to postpone one or more doses. Because it is impossible to predict the degree of protection conferred by partial doses, this option is not recommended. Consequently, consideration has been given to the possibility of postponing one or more doses of the current immunization schedule, which calls for the administration of DTP vaccine at 2, 4, 6, and 18 months of age, with a fifth dose at 4-6 years of age.

With pertussis, there is a significant risk of infection in infancy and early childhood, with 2,463 cases reported in 1983 (51% of them among infants under 1 year old). Additionally, infants are more likely to suffer complications or death from pertussis than are older children. Consequently, it is critical to continue providing protection against pertussis to infants. The first three doses of DTP vaccine provide protection against pertussis in 70%-90% of recipients and immunity to

*Diphtheria and Tetanus Toxoids and Pertussis Vaccine, Adsorbed.

diphtheria and tetanus in over 90% of recipients. The doses given at 18 months and at 4-6 years of age enhance protection through the preschool and early school years, respectively.

Taking all these factors into account, interim postponement of the doses of DTP vaccine given at 18 months and at 4-6 years of age could achieve substantial savings in the rate of DTP vaccine use, while still protecting those at greatest risk of these diseases. To have enough vaccine to provide initial protection to all young infants unil larger quantities of DTP vaccine are again available, it will be necessary to begin this approach immediately.

After consultation with members of the Immunization Practices Advisory Committee and the Committee on Infectious Diseases of the American Academy of Pediatrics, the following interim recommendations are made:

1. EFFECTIVE IMMEDIATELY, ALL HEALTH-CARE PROVIDERS SHOULD POSTPONE ADMINISTRATION OF THE DTP VACCINE DOSES USUALLY GIVEN AT 18 MONTHS AND 4-6 YEARS OF AGE (FOURTH AND FIFTH DOSES) UNTIL GREATER SUPPLIES ARE AVAILABLE.

2. WHEN ADEQUATE DTP VACCINE BECOMES AVAILABLE, STEPS SHOULD BE TAKEN TO RECALL ALL CHILDREN UNDER 7 YEARS OF AGE WHO MISS THESE DOSES FOR REMEDIAL IMMUNIZATION.

If these recommendations are followed by all providers of DTP vaccine throughout this temporary vaccine shortage, immunity in infants will be maintained at the best possible levels. Public health-care providers and professional organizations throughout the United States have been notified and are being urged to follow these recommendations.

Adapted from the Morbidity and Mortality Weekly Report (MMWR), December 14, 1984/Vol. 33/No. 49.

PLAN OF ACTION FOR THE STATE OF MARYLAND

Immediately following the issuance of the above recommendations, the Maryland Department of Health and Mental Hygiene (DHMH), the Med-Chi Subcommittee on Immunization and Infectious Diseases, and the Chairman of the Maryland Chapter of the American Academy of Pediatrics, unanimously agreed to endorse and adopt as soon as possible the emergency recommendations. All Maryland Health Officers have requested to put into effect the changes necessary to implement the new recommendations; a Press Release containing the essential facts has been issued to the media by the DHMH; the State Department of Education and the Group Day Care Center Program have been instructed to temporarily relax enforcement of the mandated 4th and 5th DTP doses for school and day care attendance; and a direct mailing was made to all pediatricians, family practice physicians and general practitioners in the State outlining the problem and encouraging the adoption of the emergency DTP recommendations until the vaccine shortage abates. The DHMH plans to monitor very closely this situation for the next several months and will issue additional instructions if and when they become necessary.

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Low incidence of side effects
CARDIZEM® (diltiazem HCl) produces an incidence of adverse reactions not greater than that reported with placebo therapy, thus contributing to the patient's sense of well-being.

*Cardizem is indicated in the treatment of angina pectoris due to coronary artery spasm and in the management of chronic stable angina (classic effort-associated angina) in patients who cannot tolerate therapy with beta-blockers and/or nitrates or who remain symptomatic despite adequate doses of these agents.

References:
1. Strauss WE, McIntyre KM, Parisi AF, et al: Safety and efficacy of diltiazem hydrochloride for the treatment of stable angina pectoris: Report of a cooperative clinical trial. Am J Cardiol 49:560-566, 1982.
2. Pool PE, Seagren SC, Bonanno JA, et al: The treatment of exercise-inducible chronic stable angina with diltiazem: Effect on treadmill exercise. Chest 78 (July suppl):234-238, 1980.

Reduces angina attack frequency*
42% to 46% decrease reported in multicenter study.[1]

Increases exercise tolerance*
In Bruce exercise test,[2] control patients averaged 8.0 minutes to onset of pain; Cardizem patients averaged 9.8 minutes ($P<.005$).

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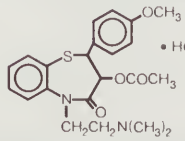
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DESCRIPTION

CARDIZEM® (diltiazem hydrochloride) is a calcium ion influx inhibitor (slow channel blocker or calcium antagonist). Chemically, diltiazem hydrochloride is 1,5-Benzothiazepin-4(5H)one,3-(acetyloxy) -5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-, monohydrochloride,(+) -cis-. The chemical structure is:



Diltiazem hydrochloride is a white to off-white crystalline powder with a bitter taste. It is soluble in water, methanol, and chloroform. It has a molecular weight of 450.98. Each tablet of CARDIZEM contains either 30 mg or 60 mg diltiazem hydrochloride for oral administration.

CLINICAL PHARMACOLOGY

The therapeutic benefits achieved with CARDIZEM are believed to be related to its ability to inhibit the influx of calcium ions during membrane depolarization of cardiac and vascular smooth muscle.

Mechanisms of Action. Although precise mechanisms of its antianginal actions are still being delineated, CARDIZEM is believed to act in the following ways:

1. Angina Due to Coronary Artery Spasm: CARDIZEM has been shown to be a potent dilator of coronary arteries both epicardial and subendocardial. Spontaneous and ergonovine-induced coronary artery spasm are inhibited by CARDIZEM.
2. Exertional Angina: CARDIZEM has been shown to produce increases in exercise tolerance, probably due to its ability to reduce myocardial oxygen demand. This is accomplished via reductions in heart rate and systemic blood pressure at submaximal and maximal exercise work loads.

In animal models, diltiazem interferes with the slow inward (depolarizing) current in excitable tissue. It causes excitation-contraction uncoupling in various myocardial tissues without changes in the configuration of the action potential. Diltiazem produces relaxation of coronary vascular smooth muscle and dilation of both large and small coronary arteries at drug levels which cause little or no negative inotropic effect. The resultant increases in coronary blood flow (epicardial and subendocardial) occur in ischemic and nonischemic models and are accompanied by dose-dependent decreases in systemic blood pressure and decreases in peripheral resistance.

Hemodynamic and Electrophysiologic Effects. Like other calcium antagonists, diltiazem decreases sinoatrial and atrioventricular conduction in isolated tissues and has a negative inotropic effect in isolated preparations. In the intact animal, prolongation of the AH interval can be seen at higher doses.

In man, diltiazem prevents spontaneous and ergonovine-provoked coronary artery spasm. It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure and, in exercise tolerance studies in patients with ischemic heart disease, reduces the heart rate-blood pressure product for any given work load. Studies to date, primarily in patients with good ventricular function, have not revealed evidence of a negative inotropic effect; cardiac output, ejection fraction, and left ventricular end diastolic pressure have not been affected. There are as yet few data on the interaction of diltiazem and beta-blockers. Resting heart rate is usually unchanged or slightly reduced by diltiazem.

Intravenous diltiazem in doses of 20 mg prolongs AH conduction time and AV node functional and effective refractory periods approximately 20%. In a study involving single oral doses of 300 mg of CARDIZEM in six normal volunteers, the average maximum PR prolongation was 14% with no instances of greater than first-degree AV block. Diltiazem-associated prolongation of the AH interval is not more pronounced in patients with first-degree heart block. In patients with sick sinus syndrome, diltiazem significantly prolongs sinus cycle length (up to 50% in some cases).

Chronic oral administration of CARDIZEM in doses of up to 240 mg/day has resulted in small increases in PR interval, but has not usually produced abnormal prolongation. There were, however, three instances of second-degree AV block and one instance of third-degree AV block in a group of 959 chronically treated patients.

Pharmacokinetics and Metabolism. Diltiazem is absorbed from the tablet formulation to about 80% of a reference capsule and is subject to an extensive first-pass effect, giving an absolute bioavailability (compared to intravenous dosing) of about 40%. CARDIZEM undergoes extensive hepatic metabolism in which 2% to 4% of the unchanged drug appears in the urine. In vitro binding studies show CARDIZEM is 70% to 80% bound to plasma proteins. Competitive ligand binding studies have also shown CARDIZEM binding is not altered by therapeutic concentrations of digoxin, hydrochlorothiazide, phenylbutazone, propranolol, salicylic acid, or warfarin. Single oral doses of 30 to 120 mg of CARDIZEM result in detectable plasma levels within 30 to 60 minutes and peak plasma levels two to three hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3.5 hours. Desacetyl diltiazem is also present in the plasma at levels of 10% to 20% of the parent drug and is 25% to 50% as potent a coronary vasodilator as diltiazem. Therapeutic blood levels of CARDIZEM appear to be in the range of 50 to 200 ng/ml. There is a departure from dose-linearity when single doses above 60 mg are given; a 120-mg dose gave blood levels three times that of the 60-mg dose. There is no information about the effect of renal or hepatic impairment on excretion or metabolism of diltiazem.

INDICATIONS AND USAGE

1. **Angina Pectoris Due to Coronary Artery Spasm.** CARDIZEM is indicated in the treatment of angina pectoris due to coronary artery spasm. CARDIZEM has been shown effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (resting angina with ST-segment elevation occurring during attacks).
2. **Chronic Stable Angina (Classic Effort-Associated Angina).** CARDIZEM is indicated in the management of chronic stable angina. CARDIZEM has been effective in controlled trials in reducing angina frequency and increasing exercise tolerance.

There are no controlled studies of the effectiveness of the concomitant use of diltiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities.

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

1. **Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
2. **Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
3. **Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
4. **Acute Hepatic Injury.** In rare instances, patients receiving CARDIZEM have exhibited reversible acute hepatic injury as evidenced by moderate to extreme elevations of liver enzymes. (See PRECAUTIONS and ADVERSE REACTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS).

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vitro bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outweigh its potential risks in this situation.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences, as well as their frequency of presentation, are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%), AV block (1.1%). In addition, the following events were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrence.

Cardiovascular:	Flushing, arrhythmia, hypotension, bradycardia, palpitations, congestive heart failure, syncope.
Nervous System:	Paresthesia, nervousness, somnolence, tremor, insomnia, hallucinations, and amnesia.
Gastrointestinal:	Constipation, dyspepsia, diarrhea, vomiting, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH.
Dermatologic:	Pruritus, petechiae, urticaria, photosensitivity.
Other:	Polyuria, nocturia.

The following additional experiences have been noted:

A patient with Prinzmetal's angina experiencing episodes of vasospastic angina developed periods of transient asymptomatic asystole approximately five hours after receiving a single 60-mg dose of CARDIZEM.

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: erythema multiforme; leukopenia; and extreme elevations of alkaline phosphatase, SGOT, SGPT, LDH, and CPK. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

OVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with oral diltiazem has been limited. Single oral doses of 300 mg of CARDIZEM have been well tolerated by healthy volunteers. In the event of overdosage or exaggerated response, appropriate supportive measures should be employed in addition to gastric lavage. The following measures may be considered:

Bradycardia	Administer atropine (0.60 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.
High-Degree AV Block	Treat as for bradycardia above. Fixed high-degree AV block should be treated with cardiac pacing.
Cardiac Failure	Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics.
Hypotension	Vasopressors (eg, dopamine or levarterenol bitartrate).

Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating physician.

The oral/LD_{50}'s in mice and rats range from 415 to 740 mg/kg and from 560 to 810 mg/kg, respectively. The intravenous LD_{50}'s in these species were 60 and 38 mg/kg, respectively. The oral LD_{50} in dogs is considered to be in excess of 50 mg/kg, while lethality was seen in monkeys at 360 mg/kg. The toxic dose in man is not known, but blood levels in excess of 800 ng/ml have not been associated with toxicity.

DOSAGE AND ADMINISTRATION

Exertional Angina Pectoris Due to Atherosclerotic Coronary Artery Disease or Angina Pectoris at Rest Due to Coronary Artery Spasm. Dosage must be adjusted to each patient's needs. Starting with 30 mg four times daily, before meals and at bedtime, dosage should be increased gradually (given in divided doses three or four times daily) at one- to two-day intervals until optimum response is obtained. Although individual patients may respond to any dosage level, the average optimum dosage range appears to be 180 to 240 mg/day. There are no available data concerning dosage requirements in patients with impaired renal or hepatic function. If the drug must be used in such patients, titration should be carried out with particular caution.

Concomitant Use With Other Antianginal Agents:

1. **Sublingual NTG** may be taken as required to abort acute anginal attacks during CARDIZEM therapy.
2. **Prophylactic Nitrate Therapy**—CARDIZEM may be safely coadministered with short- and long-acting nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.
3. **Beta-blockers.** (See WARNINGS and PRECAUTIONS.)

HOW SUPPLIED

Cardizem 30-mg tablets are supplied in bottles of 100 (NDC 0088-1771-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1771-49). Each green tablet is engraved with MARION on one side and 1771 engraved on the other. CARDIZEM 60-mg scored tablets are supplied in bottles of 100 (NDC 0088-1772-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1772-49). Each yellow tablet is engraved with MARION on one side and 1772 on the other.

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J-4044 January 1984

HOW A STUDENT WHO COULDN'T LEARN TAUGHT EVERYONE AN IMPORTANT LESSON.

Everyone thought Matthew Francisco was failing school.

But was he really?

You see, Matthew has a learning disability. And no matter what his parents and teachers did, his problem only seemed to worsen. (Matthew even started running away from home to avoid school.)

Finally Matthew's mother, Barbara, did some homework of her own and got in touch with the Minnesota Association for Children and Adults with Learning Disabilities, a United Way supported agency.

The Association helped Barbara deal with Matthew at home and his teachers deal with him at school.

Before long Matthew was solving problems in school instead of just being one.

And through her involvement with The Association, Barbara now schools other parents with learning disabled children.

This is just one of thousands of similar stories from all over the country.

And, as the Franciscos can attest, United Way does a lot in your community.

Everything from day care to foster care to care for the elderly.

And what makes it all work are generous contributions from people like yourself.

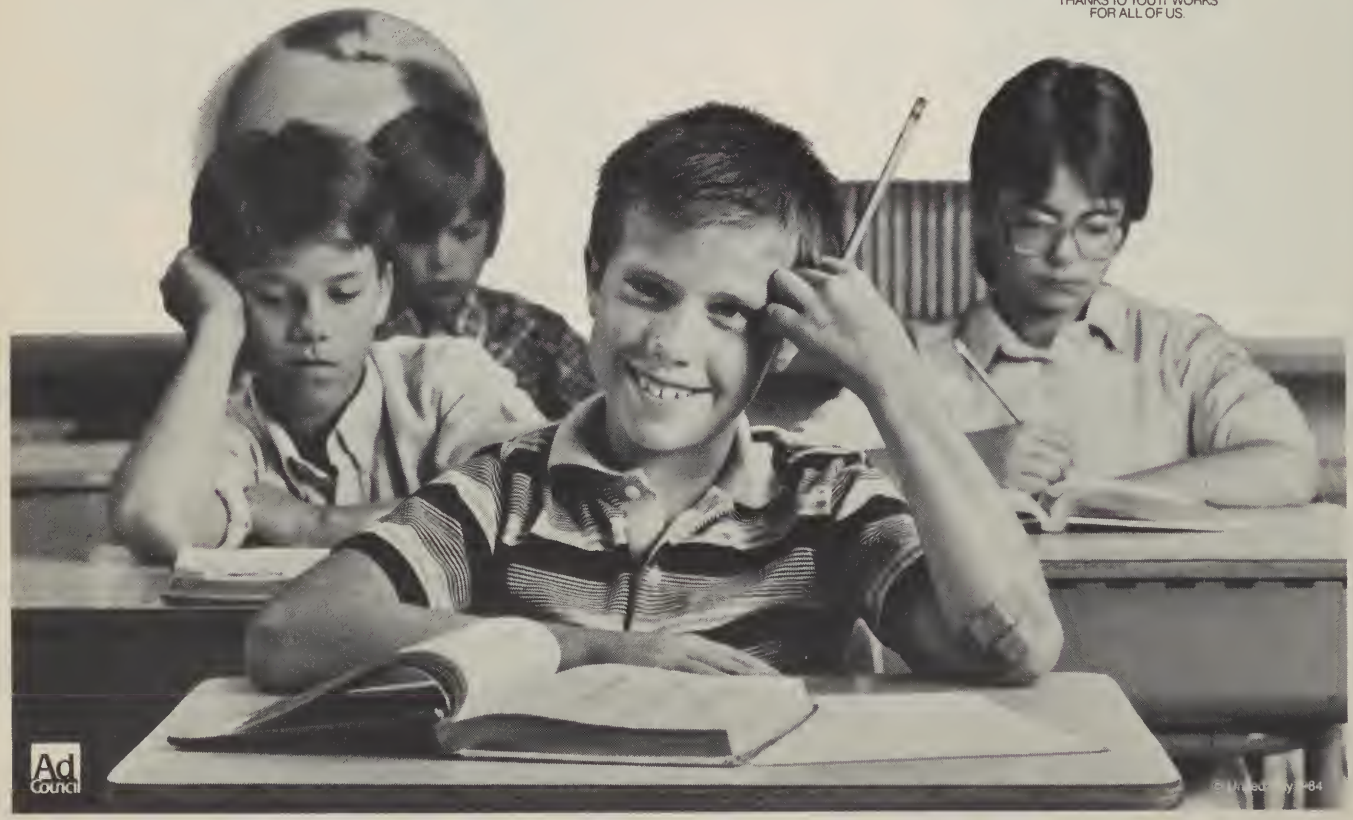
People who realize that without their help, United Way simply cannot exist.

Matthew, his parents and his teachers thank you.

So do we.

United Way

THANKS TO YOU IT WORKS FOR ALL OF US.



Ad Council

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Cancer: A Preventable Disease

The Center For Health Education, Inc. (CHE) is pleased to present this issue of the *Maryland Medical Journal* on "Cancer: A Preventable Disease." This is appropriate because our understanding of how to prevent cancer is increasing at a rapid pace as is our *knowledge* of the *treatment* of cancer. The following articles address the major risk factors responsible for most cancer morbidity and mortality as well as data supporting the need for physician involvement.

This theme also complements CHE's ongoing efforts to plan, develop, and conduct cancer prevention education with Maryland physicians. CHE was created by Maryland physicians to assist practicing physicians to take a more active role in disease prevention and health promotion. Physicians have been in the forefront of influencing lifesaving breakthroughs in the treatment of cancer and can now close the treatment-prevention gap by focusing on cancer prevention.

Articles in this issue were written by officials of the National Cancer Institute, The Johns Hopkins Medical Institutions, the American Cancer Society, scholars at MIT and Drexel University, and staff of the Center for Health Education, Inc. The introductory article by Vincent T. DeVita, Jr, MD, Director of the National Cancer Institute, provides compelling evidence that cancer may be preventable. The changing of diet and smoking behaviors is the primary target for reducing the cancer death rate in this country. To achieve a reduction in the cancer death rate, the National Cancer Institute initiated a multiphase prevention awareness campaign. The first phase is designed to create public awareness of cancer prevention messages. Concurrently, the medical profession will play a very important role by helping educate patients about the active part they can take in decreasing their cancer risk.

Peter Greenwald MD, DrPH, Director, Division of Cancer Prevention and Control, National Cancer Institute, reviews data that increasingly point to the role of dietary factors in determining cancer incidence. Dr. Greenwald presents the research basis for dietary guidelines and concludes with the hope that clinicians will be interested in the progress of cancer prevention, just as they were interested in treatment trials.

Janet L. Campbell MS, Carmine M. Valente PhD, and Albert M. Antlitz MD, of the Center for Health Education, Inc., and David M. Levine ScD, MD of the Johns Hopkins University, provide background statistics on smoking and present an overview of the physician's role in smoking cessation. Practical suggestions and strategies are offered to improve physicians' effectiveness in influencing patients' smoking behavior.

Drs. Schlaff and Rosenshein of the Department of Gynecology and Obstetrics, Johns Hopkins Medical Institutions, review the data on the roles of estrogens and oral contraceptives in promoting or inhibiting cancer. The authors conclude use of such hormones should be a decision between physician and patient.

The public's perception of cancer risk and prevention and the implications for physicians are examined by Joy Wilson MPH, Rose Mary Romano MA, and Judith Stein MA, of the National Cancer Institute. The results of their study revealed that the public's view of cancer is confused and skeptical. Many people believe that everything causes cancer, and there is not much a person can do to prevent cancer. While physicians may believe that people do not follow their advice, many studies indicate that physicians underestimate their influence on patients. It is important that physicians encourage questions and provide accurate information about the controversial issues associated with cancer.

Carmine M. Valente PhD and Janet L. Campbell MS, of the Center for Health Education, Inc., provide information about the physician's role and involvement in cancer risk reduction. Information reported in this article is drawn from group discussions conducted with a sample of Maryland physicians.

The article by John L. Young, Jr., DrPH and John W. Horm MS, Demographic Analysis Section, National Cancer Institute, compares the cancer mortality statistics of whites/nonwhites and males/females in Maryland and the United States.

The economic value of the benefits of cancer prevention programs is discussed by Andrew A. Tager AB and Edward J. Sondik PhD, of the Operations Research Branch, National Cancer Institute. They estimate the benefits of cancer prevention programs in two areas: cigarette smoking in relation to lung cancer and diet in relation to colorectal cancer.

Donna S. Cox MEd, Director, Cancer Information Service, and Kay C. VanSant, Medical Affairs Director, American Cancer Society Maryland Division, Inc., present in directory format, a compendium of community resources to assist physicians in cancer prevention.

We thank the authors for their contribution to this issue of the *Journal* and the Office of Cancer Communications, National Cancer Institute, for their interest and support in the planning and preparation of this special issue.

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Cancer as a Preventable Disease

VINCENT T. DeVITA, Jr., MD

Dr. DeVita is Director, National Cancer Institute

Historically, medicine's approach to cancer has been to search for its cause and to find better ways to treat it. In 1985, we are as committed to those searches as ever. Now, however, we have compelling evidence that cancer may be preventable using tools and information at hand.

Based on all we learned about cancer in the last decade, the National Cancer Institute (NCI) formulated a national goal: to reduce the cancer death rate in this country by half by the year 2000. That means reducing the cancer death rate from its 1980 rate of 168 deaths per 100,000 to 84 deaths per 100,000 over the next 15 years. We believe this is a reasonable and reachable objective. While diet- and smoking-related cancers are our primary targets for reducing the cancer death rate in this country, they are not the only preventable cancers.

Diet Recommendations

We make two diet recommendations we believe will significantly reduce cancer incidence and mortality. These are: *increase dietary fiber intake* in the form of fruits, vegetables, and whole-grain cereals, and *reduce dietary fat intake*. Data in support of these recommendations are increasing.

Fiber Foods high in dietary fiber appear to protect against some forms of cancer, particularly colon cancer. This protective effect is seen even when dietary fat intake is high. In one study, for example, milk fat intake was found to be about the same for individuals in rural Finland and in urban Copenhagen. But the Finns, who eat large amounts of high-fiber, unrefined rye bread, had a much lower incidence of colon cancer[1] even though they have a high incidence of coronary artery disease due to their high fat intake.

Other studies have shown an inverse correlation between the consumption of vegetables and the occurrence of colon cancers.[2] A study of esophageal cancer has suggested that deficiencies of a number of micronutrients, including those found in fruits and vegetables, may increase risk for that cancer.[3] A diet high in fruits and vegetables is also likely to be high in carotenoids, another group of dietary components that appears to protect against some cancers.

Exactly how fiber exerts its protective effects is not altogether clear. It may do so by speeding the transit time of fecal matter through the bowel, thus decreasing the time that food carcinogens stay in contact with bowel walls. By increasing the bulk of the stool, fiber may decrease the concentration of fecal mutagens and carcinogens.[4] It also has been postulated that dietary fiber intake decreases the production of mutagens in the stool.[5] A very potent mutagen, fecapentaene, is found in the feces of 15 to 20 percent of individuals at high risk of colon cancer.[6,7] This substance, produced by common intestinal microflora, appears to be mutagenic, in the Ames test, at a level comparable to beno(a)pyrene. Fecapentaene appears to increase with the amount of fat in the diet and to decrease with the amount of fiber.

The American diet typically includes only 15 to 20 grams of fiber a day; we recommend that individuals increase the fiber content of their diet, to 25 to 30 grams a day.

Fats Surveys of various populations in this and other countries suggest a link between dietary fat intake and some cancers, particularly those of the breast, colon, endometrium, and prostate gland.

Animal studies tend to confirm these associations. A link between per capita fat intake and breast cancer risk also is supported by a number of international studies.

Correlations of international incidence and death rates with diet components indicate that colon cancer, and to a lesser extent, rectal cancer, are associated with total dietary fat intake. Some case-control studies confirmed this association.

Both prostate cancer incidence and dietary fat intake are higher among Japanese living in Hawaii (who eat a more "American" diet) than among Japanese living in Japan. High incidence of prostate cancer also has been linked with consumption of animal fat and protein among other ethnic groups in Hawaii.

There is some evidence that obesity is associated with increased risk of breast cancer, leading to speculation that high dietary fat intake contributes to increased risk. Links between breast cancer and high dietary fat intake have been seen in studies of Seventh-Day Adventists, in the Hawaiian studies, and in studies in Canada.

Total fat intake accounts for about 40 percent of total calories in the U.S. diet. In Japan, where risk of colon cancer and breast cancer are considerably lower than in this country, fats account for only about 20 percent of total calories in the diet.

We recommend that Americans decrease their total dietary fat intake from 40 percent to 30 percent of total calories. Meat, eggs, dairy foods, and oils used in cooking and on salads are the chief sources of fat in the American diet. Most population studies of dietary fat intake do not discriminate between saturated and unsaturated fats. In addition, consumption of the two often goes hand-in-hand.

Smoking

We estimate that more than 100,000 persons die each year from lung cancer. It is the principal cause of cancer mortality for men in this country, and lung cancer is rapidly overtaking breast cancer as the prime cause of cancer among U.S. women. Since more than 85 percent of all lung cancers are causally related to cigarette smoking, this cancer is one of the most preventable forms we can identify. The five-year survival rate for persons with lung cancer is 12 percent.

Cigarette smoking is also a major cause of cancers of the larynx, oral cavity, and esophagus, and smoking is a contributory factor for cancers of the bladder, pancreas, and kidney.

The following statistics were collected by the NCI's Surveillance, Epidemiology and End Results Program (SEER):

- Tobacco's contribution to all cancer deaths is estimated to be 30 percent, accounting for the deaths of approximately 130,000 Americans each year.
- It was estimated that 13,000 individuals would die in 1983 from laryngeal and oral cancers. Fifty to 70 percent of these deaths were believed to be causally related to smoking.
- For 1983, estimates were that 8,500 deaths would be due to esophageal cancer. Only 4 percent of these patients live five years or more after diagnosis. Most patients die within six months. Cigarette smoking is estimated to be a factor in more than half these deaths.
- It was also estimated in 1983 that 56,000 persons would develop bladder and kidney cancer; that more than 19,000 persons would die from these cancers; and that 30 to 40 percent were thought to be smoking related.
- More than 25,000 persons developed cancer of the pancreas in 1983, and nearly 23,000 died from it. These cancers also are linked to smoking.

Research in recent years has contributed substantial information about smoking behavior and risk:

- Nonwhites are more likely to smoke than whites, by a considerable margin.
- Smoking prevalence rates for blacks are higher than for all other racial groups for which data are available.
- Smoking prevalence is especially high among blue-collar workers and the unemployed, and the prevalence of smoking among men decreases as income level increases.
- In specific occupational settings, the synergistic effect of smoking and exposure to a known carcinogen, such as asbestos, results in a multiplied risk of lung cancer that is more than ten times greater than for the nonsmoker exposed to asbestos.

Smokeless tobacco is *not* a safe substitute for cigarette smoking. An NCI study of the high incidence of oral cancers among women in the Southeastern United States[8] showed a strong association with the practice of "snuff dipping" among these women.

On the plus side, there is evidence that recommendations to stop smoking are being heeded by some population groups, including American women.

Other Causes of Cancer

Alcohol-related cancers are estimated to be responsible for 3 percent of cancer deaths in this country. Among these are cancers of the mouth, pharynx, larynx, and esophagus.[9]

Viruses are believed to account for 5 percent of cancer deaths. Among these are cancer of the uterine cervix, connected with herpesvirus, and cancer of the liver, associated with hepatitis infections. Most recently, we have learned of the human T-cell leukemia/lymphoma virus (HTLV-I) associated cancers.

Occupational exposures probably are responsible for at least 4 percent of cancers. Among these are cancers of the bladder and of the brain associated with exposure to carcinogens during manufacturing processes.

Excess sun exposure is estimated to be the most common cause of all skin cancers, although skin cancer, rarely fatal, accounts for only 3 percent of cancer deaths. These include invasive squamous cell carcinoma, which is directly associated with sun exposure, and melanoma skin cancer, which is indirectly connected to sun exposure.

How Does NCI Expect to Prevent Cancer Deaths?

Since 1982, NCI developed and increased its research efforts in prevention through diet modification and chemoprevention. Laboratory and clinical studies identified a number of potential chemopreventive agents, in addition to dietary fiber. These agents include micronutrients such as vitamin A; its derivatives, and retinoids, and its precursors, the carotenoids; vitamins C and E; and selenium. All have been found to halt or to reverse the cancer process in laboratory and animal studies. Building on basic research in prevention over the past ten years, we are now studying such agents in more than 20 clinical studies in efforts to prevent various cancers. By 1990 we should be able to determine whether certain types of cancer can be prevented by adding chemopreventive agents to the diet.

Last March, Health and Human Services Secretary Heckler helped us launch our Prevention Awareness Campaign. Note that our campaign is not simply "prevention" but "prevention awareness."

A national survey conducted recently by NCI showed clearly that perceptions about cancer have failed to keep pace with the progress of medical sciences. *Almost half the respondents in this survey failed to identify individual prevention as a way to reduce cancer risk. More than 45 percent agreed with the statement, "there is not much a person can do to prevent cancer."*

The charge to physicians, therefore, is a double one: first, to heighten understanding among patients that they can take steps to reduce cancer risk, and second, what steps can be taken.

The first phase of the prevention awareness campaign announced by Secretary Heckler relies primarily on mass media efforts to create public awareness of these NCI prevention messages:

- Don't smoke or use tobacco in any form.
- Include fresh fruits, vegetables, and whole grain cereals in your daily diet.
- Eat foods low in fat.
- If you drink alcoholic beverages, do so only in moderation.
- Avoid unnecessary X-rays.
- Health and safety rules of your workplace should be known and followed.
- Avoid too much sunlight; wear protective clothing; use sunscreens.

This phase of the campaign also encourages the public to call NCI's 1-800-4-CANCER line. These calls come into NCI's Bethesda-based inquiries staff and into NCI's 22 Cancer Information Services connected with Comprehensive Cancer Centers throughout the country.

In the second phase, program emphasis will move from the general public toward higher risk populations. Again, program messages will emphasize risk factors and ways to minimize them.

Concurrently, the medical profession can take a very large and important part in helping to educate patients about the active role they can take in their own health care. All practicing physicians have the opportunity to educate their patients about the facts that one's behavior can help decrease cancer risk and that changes in behavior and habits can effect these decreases in cancer risk.

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Diet and Cancer Prevention

PETER GREENWALD MD, DrPH

Correspondence and reprint requests: Peter Greenwald, MD, Director, Division of Cancer Prevention and Control, National Cancer Institute, Building 31, Room 4A32, 9000 Rockville Pike, Bethesda, MD 20205

The relationship between diet and cancer incidence has not yet been precisely defined, but data increasingly point to dietary factors as having a role in determining cancer incidence. Published estimates of the percentage of reduction in cancer deaths that could be accomplished by dietary changes have ranged as high as 60 to 70 percent,[1,2] but 30 percent seems a reasonable, conservative estimate.

Physicians in Maryland recognize not only the role of behavioral risk factors in disease prevention but also their own role in influencing such behaviors. In a 1983 survey of Maryland physicians by the Center for Health Education, Inc.,[3] the majority of respondents indicated that physicians definitely should try to modify people's behaviors in an effort to minimize risk factors, and that it was part of their responsibility to educate patients about these factors.

Respondents recognized diet as important in promoting the health of an individual; the majority indicated it was important to eat a balanced diet, avoid excess caloric intake, and avoid foods high in saturated fats. The physicians reported, however, their patients were not very successful in modifying their diets and that a large percentage were overweight, although concerned about cancer.

Physicians did seem interested in helping patients reduce their risk for cancer by improving their diet and nutrition. The majority reported they would be likely to take continuing medical education courses in cancer risk reduction and in diet and nutrition.

If physicians in Maryland were to become more effective in influencing their patients to improve dietary habits as a means of reducing risk for cancer, what are the potential effects on cancer incidence and mortality? The cancers most related to diet are breast cancer, colon and rectal cancers, and perhaps prostate cancer. Thus, if Maryland physicians advised their patients on the guidelines described below, the potential effect overall could be a substantial reduction in mortality from these cancers.[4]

Interventions for the Physician

In 1979, the National Cancer Institute, using epidemiologic studies conducted during the 1970s as a basis, developed and published a set of dietary principles that included a reduction of dietary fat, an increase in dietary fiber, and moderation in alcohol consumption. In 1980, the National Academy of Sciences studied all available information on diet and cancer incidence, and summarized the state of knowledge in this area.[5] A conclusion of the Academy's report was that although it may never be possible to specify a diet that would protect everyone against all forms of cancer, it is possible to formulate interim dietary guidelines that are consistent with good nutritional practices and that are likely to reduce the risk of cancer. Individuals can follow four of these guidelines on their own. Physicians might suggest them to patients.

Interim Dietary Guidelines

Reduce consumption of both saturated and unsaturated fats in the average U.S. diet. There is sufficient evidence that high-fat consumption is linked to increased incidence of certain common cancers (notably breast and colon cancer) and that low-fat intake is associated with a lower incidence of these cancers. An appropriate and practical target is to reduce the intake of fat from its present level of approximately 40 percent to 30 percent of total calories in the diet. The scientific data do not provide a strong basis for establishing fat intake at precisely 30 percent of total calories. Indeed, the data could be used to justify an even greater reduction, but the suggested reduction is a moderate and practical target, and is likely to be beneficial.

Include fruits, vegetables and whole grain cereal products in the daily diet. In epidemiological studies, frequent consumption of these foods has been inversely correlated with the incidence of various cancers. Results of laboratory experiments have supported these findings in tests of individual nutritive and nonnutritive constituents of fruits (especially citrus fruits) and vegetables (especially carotene-rich and cruciferous vegetables).

Minimize consumption of foods preserved by salt-curing (including salt-pickling or smoking). In some parts of the world, especially China, Japan, and Iceland, populations that frequently consume salt-cured (including salt-pickled) or smoked foods have a greater incidence of cancers of some sites, especially the esophagus and the stomach. In addition, some methods of smoking and pickling foods seem to produce higher levels of polycyclic aromatic hydrocarbons and N-nitroso compounds. The compounds cause mutations in bacteria and cancer in animals, and are suspected of being carcinogenic in humans.

Consume alcoholic beverages in moderation, if at all. Excessive consumption of alcoholic beverages, particularly combined with cigarette smoking, has been associated with an increased risk of cancer of the upper gastrointestinal and respiratory tracts. Consumption of alcohol is also associated with other adverse health effects.

A complementary set of guidelines, "Nutrition and Your Health: Dietary Guidelines for Americans," was published by the United States Department of Agriculture and the United States Department of Health, Education, and Welfare in 1980.[6] These seven suggestions are similar to those of the National Academy of Science. Both sets of guidelines have benefits not only in reducing risk for cancer but also for heart disease.

Dietary Guidelines for Americans

- Eat a variety of foods.
- Maintain ideal weight.
- Avoid too much fat, saturated fat, and cholesterol.
- Eat foods with adequate starch and fiber.
- Avoid too much sugar.
- Avoid too much sodium.
- If you drink alcohol, do so in moderation.

SOURCE: *Nutrition and Your Health.* U.S. Dept. of Agriculture and U.S. Dept. of Health, Education, and Welfare, 1980

An individual wishing to reduce risk for the spectrum of diseases by adopting dietary guidelines might find the easiest way to implement diet changes is to learn a few simple rules about foods rather than to make an extensive effort to learn menus. The American Health Foundation has developed such a set of rules, shown in the Table. Foods are grouped into those to choose freely, those to limit, and those to avoid.

As mentioned, the relationship between diet and cancer has not yet been precisely defined; nonetheless, existing data do point to a relationship between dietary fat and breast cancer, dietary fiber and colon and rectal cancers, and vitamin A and epithelial cancers.

Causal Evidence Linking Dietary Fat and Breast Cancer

A number of studies show a consistent relationship between dietary fat and human breast cancer. Phillips[7] compared Seventh-Day Adventists with breast cancer to Seventh-Day Adventist controls and found roughly

Table. Food at a Glance

	Choose	Limit	Avoid
Fats & Oils	Fats within daily allowance: low-fat salad dressings, low-fat mayonnaise, vegetable oils, butter, margarine	Fats within daily allowance: low-fat salad dressings, low-fat mayonnaise, vegetable oils, butter, margarine	All other fats, including regular salad dressings, cooking fats, mayonnaise, fried nuts, olives
Dairy Foods	Skim milk: fluid, evaporated & powdered; buttermilk (skim); fat-free yogurt; cottage cheese (1% fat, rinsed); skim farmer cheese; sapsago cheese	Low-fat and part skim (1% & 2%) milk & milk products: yogurt, cottage cheese, frozen yogurt, farmer cheese, ricotta cheese; sherbert; ice milk	Whole (homogenized) milk & whole milk products: yogurt, cottage cheese, ricotta cheese; cream, non-dairy creamers; sour cream; cream cheese; hard cheeses
Meat & Protein	Lean veal, fish, poultry; legumes (beans, lentils, peas); tofu & tempeh; egg whites	Red meat, duck, lamb, egg yolks, nuts, peanut butter	Sausage, bacon, luncheon meat, hot dogs, fried meat, fried fish
Bread, Cereals & Other Starches	Whole grain breads, rolls, bagels, cereals, pasta, brown rice, potatoes with skins	Muffins, tea biscuits, crackers	Doughnuts, croissants, commercial baked goods, fried potatoes, fried rice, potato chips, corn chips
Fruits & Vegetables	All fresh and frozen fruit and vegetables	Canned fruit, avocado	Coconut
Sugar & Alcohol		Honey, molasses, maple syrup, jams, hard candy; alcoholic beverages	Sugar, chocolate, caramel, toffee, nougat
Beverages	Juice; herbal tea; club soda, seltzer, water	Drinks containing caffeine (for example, coffee, tea, hot chocolate, cola); sweetened (naturally & artificially) carbonated beverages not containing caffeine	Drinks made with ice cream or cream

SOURCE: Mahoney Institute for Health Maintenance, American Health Foundation

twice the risk of breast cancer for patients who frequently ate fried foods as compared to those who less frequently ate these foods. In a survey of 4,657 Hawaiians from five different ethnic groups, Kolonel and colleagues[8] found a strong correlation between breast cancer incidence and age-adjusted mean daily intake of total fats, animal fats, saturated or unsaturated fats. A National Cancer Institute study compared the dietary fat intake of 577 breast cancer patients to that of 826 controls and found that persons in the highest quartile for beef or pork consumption had 2.7 times the breast cancer risk of those in the lowest quartile.[9] Elevated risk also was found for women in the upper quartile eating creams and desserts or animal fats. Miller and colleagues[10] found elevated risk ratios for total fat and selected types of fat for both premenopausal and postmenopausal breast cancer patients. The association was for fat (but not for total calories), and reliability of the dietary surveys was suggested through the use of several different methods. Thus, taken together, there are similar results from independent investigators using somewhat different methodologic approaches to the dietary fat and breast cancer question.

Epidemiologists use the words "relative risk" as a key indicator of strength of an association. Wynder and colleagues[11] described international variations in dietary fat and age-adjusted breast cancer mortality. Countries with the highest fat consumption also have high breast cancer mortality. A comparison of countries with half the fat intake of countries with the highest fat intake shows that the breast cancer mortality for the former is a bit below half that of the latter. Thus, as hypothesized, fat intake is a major determinant of breast cancer risk. Based on international variation one might expect that reducing calories from fat by half might have a major impact on the breast cancer incidence rate.

Specificity of evidence or the absence of good alternative hypotheses increases the likelihood that a hypothesis is valid. For breast cancer, no solid alternative hypotheses exist that exclude associating fat as a risk for this cancer. However, a search for interacting factors or alternative hypotheses is certainly still of major importance.

Time relationships also are important in considering causality. For dietary factors it is obvious that specific dietary behaviors have generally been present throughout most of an individual's life and certainly before the clinical onset of cancer.

Agreement between human epidemiologic studies and mechanistic studies in animals sometimes is called "biologic plausability." This is present for the dietary fat-breast cancer relationship. For example, in 1942 Tannenbaum[12] showed that mice with high-fat diets developed many more DBA-induced mammary tumors than did mice with low-fat diets. More sophisticated studies of this sort have been done by Carroll *et al.*[13] These investigators showed that diets high in corn oil resulted in many more DMBA rat mammary tumors than did diets low in corn oil. This effect was true for different levels of the carcinogen, but the difference was most marked with lower levels of carcinogen. Further, Carroll showed that the primary effect was that of inhibiting tumor promotion. Thus, the major benefit of low dietary fat occurred after, rather than before, injection of the DMBA carcinogen. Many other types of metabolic studies including those related to bile steroids and hormones support the possibility that high-fat diets increase cancer risk.

The convergence of this evidence linking dietary fat and breast cancer is the basis for public recommendations and for initiating human intervention trials in current research. An initial human trial supported by the National Cancer Institute aims to study the effects of a 20 percent-fat diet as the intervention compared to the typical American diet in which approximately 40 percent of calories are derived from fat. The trial will be of women at high risk for developing breast cancer. The endpoint will be a reduced incidence of breast cancer. Study subjects will be women who have a first-degree relative with a history of breast cancer and who have had a first pregnancy at 30 years or more of age; or women who have had two or more breast biopsies for benign disease; or women who have two or more first-degree relatives with a history of breast cancer. The human trial will test whether reducing dietary fat will slow or halt the promotion phase of carcinogenesis and reduce the incidence of breast cancer in the study population. This trial will evaluate the specificity of the epidemiologic studies and will test whether the impact of a low-fat diet intervention in humans duplicates animal model results. This trial also will provide insights into strategies for influencing eating behavior and will document the safety of the study diet.

Research Leads on Dietary Fiber and Colon Cancer

Increasing dietary fiber may have major benefits in reducing colon cancer risk. Dietary fiber, a largely indigestible component of food, provides bulk in the diet. It is found in vegetables, fruits, and whole grain cereals and includes indigestible carbohydrates and carbohydratelike components of food such as cellulose, lignin, hemicelluloses, pentosans, gums, and pectins. Fiber consists of plant walls and nonnutritive residues (nonnutritive residues include all substances resistant to animal digestive enzymes).

Recently a great deal of scientific attention has been directed at elucidating whether dietary fiber protects against colon cancer. A 1978 study[14] found that fiber appeared to offer some protection against tumor development in rats given a digestive tract carcinogen. Rats given the carcinogen were fed different amounts of cellulose. Those rats given the least amount of cellulose developed the highest number of intestinal tumors. In addition, the observed incidence of tumors decreased with the increase in dietary bulk provided by the cellulose. In other studies, increased dietary fiber resulted in a decrease in mutagenic activity in human feces.[15] Other laboratory studies have shown that consumption of specific sources of fiber (bran and cellulose) reduces the tumorigenic potential of certain chemical carcinogens.[16-20]

The epidemiologic data on fiber relate primarily to its possible protective effect against colon cancer. (It also has been noted that intestinal diseases such as appendicitis, diverticulosis, and colonic polyps, as well as colon cancer, occur less frequently in populations that consume large amounts of fiber in the diet.) A high-fiber intake has been correlated with larger, softer stools, more frequent defecation, and more rapid intestinal transit times.[21-23] Epidemiologic studies have shown that a Finnish population at low risk for colon cancer has more fiber in the diet than do higher risk people in New York or Copenhagen.[24,25] Colon cancer patients in Israel also had less fiber in the diet than did other Israelis.[26] In the United States, colon cancer patients in the Bay Area of San Francisco were less likely to have eaten fiber and more likely to have eaten fat than were controls,[27] and the Mormon and Seventh-Day Adventist groups have high fiber diets and are low colon cancer risks.[28,29] In a study that assessed the individual components of fiber, there was an inverse correlation between the incidence of colon cancer and the consumption of the pentosan fraction of fiber (found in whole wheat products).[30]

Various mechanisms have been proposed for the protective effect of fiber against cancer: decrease in the concentration of carcinogens in the stool by increasing the bulk; decrease in transit time, thereby decreasing the contact time between carcinogen and tissue; and alteration of the proportion of various bacterial species in the bowel.[31]

Because the composition of dietary fiber is complex, research is complicated. Earlier studies primarily focused on the intake of "crude fiber" (material that resists acid hyrolysis) as opposed to "total fiber" (material that resists digestive enzymes). Since crude fiber contains only cellulose and lignin, the earlier studies tended to underestimate the fiber content and provided incomplete data on the amount and specific type of fiber consumed by study subjects. Furthermore, the initial fiber content of food may change with its preparation. More specific studies are needed to assess the effect of individual components of dietary fiber rather than total fiber intake.

Dietary Vitamin A and Cancer

Beta-carotene is present in leafy, green, and yellow vegetables. It is converted to vitamin A in the digestive tract.

Substantial laboratory and human studies have led to the hypothesis that ingestion of dietary vitamin A, beta-carotene (the precursor of vitamin A), and synthetic retinoids (analogues of vitamin A) is inversely related to cancer. A historically important laboratory study was done by Lasnitzki,[32] who developed a method for growing mouse prostate cells on a glass, for transforming these cells to cancer cells by adding a carcinogen, and for inhibiting the transformation by adding vitamin A. She also inhibited a later stage of cancer cell development by adding vitamin A. Subsequently, other researchers showed that retinoic acid inhibits and reduces cancer.[33,34]

Epidemiologic data support the vitamin A hypothesis. About 20 studies in various parts of the world suggest an inverse association between eating foods containing vitamin A or beta-carotene and various types of human cancer; risk is thereby reduced 30 to 50 percent. For example, several case-control epidemiologic studies show lower vegetable consumption or lower estimates of vitamin A intake among cancer patients than among controls. This relationship is supported by three cohort studies that observed a negative association between lung cancer and an index of vitamin A, the first by Bjelke[35] in a study of 8,278 Norwegian men. Hirayama[36] made a similar observation in a study of 265,118 Japanese adults and suggested that ex-smokers might particularly benefit from daily vegetable consumption. Shekelle *et al.*[37] found dietary carotene to be inversely related to lung cancer in 2,107 American men.

Prospective studies in 1980 and 1981 reported an inverse correlation between cancer risk and total blood retinol in frozen, stored sera. Wald *et al.*[38] followed 16,000 men from whom serum samples had been collected and stored. After 3 to 5 years of follow-up, 86 of the men had developed cancer. Kark *et al.*[39] followed 3,102 individuals from Evans County, Georgia, for 12 to 14 years. Serum vitamin A (retinol) levels were measured on the stored sera of 85 cancer patients and 174 matched controls. These also showed an inverse correlation between blood levels and cancers of various types.

Later studies could not confirm these results. Willett

et al.[40] measured retinol-binding protein, vitamin E, and total carotenoids in serum collected in 1973 from 111 participants in the Hypertension Detection and Follow-up Program who were free of cancer at the time but diagnosed as having cancer during the subsequent five years. When compared to matched controls, no differences were found in mean values for retinol-binding protein or for total carotenoids. Serum vitamin E levels were somewhat lower in persons who later developed cancer partly because of the confounding effects of vitamin E varying with serum cholesterol levels. In an earlier report on the same group,[41] the mean selenium level of persons with cancer was shown to be lower than for controls. The association between low selenium level and cancer was strongest for gastrointestinal and prostatic cancers. Given that cancer risks were highest for the low selenium groups that were also low in vitamins E and A, there may have been some interaction between levels of vitamin A and E and selenium.

The mixed evidence from studies of serum vitamin A is not surprising, since homeostatic control maintains serum retinol within a narrow range and serum levels may not reflect what is in the tissues.[42] The failure to find a relationship to blood levels in the more recent studies may reflect in part the narrow range of differences between individuals. Except in marked deficiency states, blood retinol levels do not indicate total body load. More important to emphasize is the fact that concentration differences at the largest tissues may be far more relevant, and these have not been examined. In most studies to date, only total carotenoids, rather than the active (and less stable) beta-carotene, have been measured. Beta-carotene varies with blood lipids and, depending on diet, may account for only one-fifth of the total circulating carotenoids. Thus, the validity of these studies of blood levels of retinol and carotene to test the question of a protective effect of dietary retinol and beta-carotene against cancer is uncertain. Perhaps newer laboratory techniques will improve the results of prospective studies based on frozen sera, but it seems that human intervention trials will be needed to obtain a definitive answer on the benefits of these compounds.

In the only intervention trial reported to date, Gouveia *et al.*[43] examined the effect of the synthetic retinoid Etretinate on 34 heavy smokers with bronchial metaplasia. The index of metaplasia scores dropped significantly in the 12 study subjects who completed six months of treatment. This preliminary study will need confirmation because the number of cases is small and the precision of the metaplasia score is uncertain.

As a means of following up on these leads, NCI has funded about 20 human trials. These trials comprise studies of prevention in general populations, in high-risk groups, for precancerous lesions, and of new primary cancers.

Conclusion

Increasing dietary fiber and decreasing the percentage of calories from fat, while eating a variety of foods, offers the best hope of reducing the incidence of colon, breast, and perhaps other cancers. The current position of cancer prevention research is in some ways analogous to that of treatment in the early 1950s. The research challenge in treatment looked formidable at that time, but a research process was developed and substantial advances have been made in treatment. Likewise, research of diet and prevention is in an early stage; nevertheless, because of the research leads, the research community is optimistic about making advances in the near future that will further clarify the role of diet in the initiation or promotion of cancer. The hope is that clinicians will be interested in the progress of cancer prevention, just as they were interested earlier in treatment trials, and will take an active role in educating and motivating their patients to reduce their risk for cancer through dietary modifications.

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Using Four Simple Steps, Physicians Do Influence Smoking Behavior

JANET L. CAMPBELL MS, CARMINE M. VALENTE PhD, DAVID LEVINE ScD, MD, and ALBERT M. ANTLITZ MD

Janet L. Campbell is a Health Educator and Carmine M. Valente is the Executive Director of the Center for Health Education, Inc. Dr. David Levine is Professor of Behavioral Science and Health Education, School of Hygiene and Public Health at The Johns Hopkins University. Dr. Albert M. Antlitz is a cardiologist and Chairman of the Board of Directors for the Center for Health Education, Inc.

Few people in the United States are not aware that cigarette smoking is a health hazard. It may surprise many, however, to know that **cigarette smoking is the largest preventable cause of illness and premature death in the United States.**[1] Thirty percent of *all* cancer mortality (about 129,000 deaths per year) is related to tobacco use.[2] In addition, the number of lung cancer deaths ascribable to tobacco is increasing by approximately 4,000 per year.[3] For cigarette smokers, the incidence of lung cancer is more than ten times greater by late middle age than in nonsmokers.[4] In Maryland, the American Cancer Society estimates that 2,500 individuals died in 1984 of lung cancer.[5] Accumulating evidence suggests that smoking doubles the incidence of cancer of the bladder and probably also of the pancreas and is associated with a more moderate increase in kidney cancer.[6]

Smoking contributes to other diseases. Surgeon General C. Everett Koop stated that heart disease among cigarette smokers is causing nearly one death in ten in the United States. On average, cigarette smokers have a 70 percent greater rate of coronary heart disease than do nonsmokers,[7] representing up to 170,000 deaths per year.[8] There is an enormous amount of evidence suggesting that smokers face a heightened chance of stroke, emphysema, bronchitis, allergies, and stomach ulcers.[9]

In addition, preliminary results of a study by the National Institute of Child Health and Development show that sudden infant death syndrome, the cause of death of 6,500 U.S. babies annually, is more likely among infants of mothers who smoke.[10] A University of Maryland study has shown that pregnant women who cut down on smoking give birth to larger babies than women who do not.[11] Women who are heavy smokers generally start menopause three years earlier than nonsmokers, as well as have a higher chance of developing skin wrinkles and gum disease.[12]

Research abounds suggesting the link between tobacco and death and disease. On the positive side, the proportion of men who smoke has dropped from 52.1 percent in 1963 to 37.9 percent in 1983. A similar decline for women has also been noted, 34.2 percent to 29.8 percent.[13] However, lung cancer, once a rarity in women, is expected to surpass breast cancer this year. In addition, smoking among teenage girls increased from 8.4 percent to 12.7 percent between 1968 and 1979.[14] It is disheartening that some 53 million Americans of all ages still smoke.[15]

The costs to society due to smoking are enormous. The National Center for Health Statistics has calculated that each year an excess of nearly 150 million days in bed are due to the extra amounts of illness experienced by cigarette smokers. These smokers have 81 million excess days of absenteeism. Though it is difficult to accurately calculate the economic costs of tobacco use, one estimate for 1976 placed direct health care costs at $8 billion and productivity losses at $19 billion.[16] A study in Minnesota (a state with approximately 3,000 fewer new cancer cases in 1984 than Maryland)[17] estimated that the cost of treating smoking-related illnesses constituted 7.5 percent of the state's total health bill. Nearly 457 million packs of cigarettes were sold in Minnesota in 1983 at an average cost of 94 cents. Smoking-related health care costs translated to 89 cents per pack, and this figure did **not** include the health costs of former smokers or those associated with lost productivity and income.[18]

The serious health disadvantages and the tremendous economic costs due to tobacco use point strongly to the need for greater efforts aimed at smoking prevention and smoking cessation.

Physician Potential

Though there exists a wide variety of organizations, agencies, and programs concerned with smoking prevention and cessation, physicians are in an ideal position to influence their patients' smoking behavior. Studies have revealed that at least 70 percent of North Americans see a physician at least once a year.[19,20] Consequently, 38 million of the 54 million smoking adults in the U.S. could be reached annually with a smoking-cessation message delivered by a physician.[21] In the urban areas of Maryland, the percentages are even higher with 75 to 80 percent of the population seeing a physician at least once yearly.[22] What makes this contact particularly significant is the strong influence physicians can have on their patients' behavior. Though physicians often underestimate this influence, 70 percent of heavy smokers in one survey stated they would **stop** smoking if urged to do so by their physician.[23] In another survey, more than 75 percent of the smokers interviewed reported they believed physician advice would be "somewhat" to "very" effective in getting them to cut down or quit smoking.[24]

The problem, however, is that the vast majority of patients state that their physicians do not tell them to stop smoking or explain the hazards of smoking.[25–27] What is surprising is that in two extensive surveys of primary care practitioners in Maryland and Massachusetts,[28,29] over 90 percent of physicians thought it very important for the health of the average person to stop

smoking. In addition, the majority of physicians believed it was part of their responsibility to try to modify patients' behavior; thought they were prepared to counsel patients about smoking cessation/reduction; and indicated they regularly gathered information from their patients about their smoking habits. For some reason, the expressed interest and concern of physicians in helping patients quit smoking is not getting across to patients. Physicians in the above surveys admitted they were not very successful in motivating patients to change behavior, and as previously stated, the majority of patients do not believe their physicians ever urged them to stop smoking.

Many reasons could be proposed for this discrepancy in communication, but laying blame on one group or another does nothing to solve the smoking problem. In the Maryland study, physicians did indicate that with appropriate support they could be up to five times more successful in changing patient smoking behavior. The type of support they requested included referral information, patient literature, risk-factor questionnaires, and education in behavior modification regarding smoking cessation. The article on page 83 by Cox and VanSant provides physicians with information on a variety of community programs designed to assist people in quitting smoking, as well as sources for patient literature. This article offers physicians suggestions as to how to modify patients' smoking behavior.

What the Physician Should Do

Numerous researchers have examined a variety of physician-led smoking interventions that have had varying degrees of success.[30–34] For the most part, however, studies show that physicians can be very influential in the area of smoking cessation. Although there are dissimiliarities in the approaches used by most investigators, research suggests that a successful physician-conducted smoking-cessation effort will consist of four components.

The basic strategy includes:

1. Documenting the patient's smoking history.
2. Setting a quit date.
3. Preparing the smoker to be a nonsmoker.
4. Reinforcing the message and monitoring the patient's progress.

Documenting. Although most physicians probably make a notation somewhere in the patient's record regarding smoking behavior, a thorough execution of this component requires that the physician implement four actions. First, the physician should assess the patient's smoking history. This includes finding out how many cigarettes a day are smoked; how many years the patient has smoked; whether the patient has ever had a job in which (s)he was exposed to asbestos, coal, or cotton fiber; if the patient's spouse smokes; and whether the patient feels that smoking has ever harmed his/her health. To save time, this assessment can be done on a printed questionnaire, but the information should be updated or reviewed at every contact with the patient so as to indicate the importance of this information to the medical record and to the patient's health.

Second, the physician should deliver a **firm** antismoking message. If possible, the message should be made personally relevant with regard to the individual's medical history. However, even light smokers with no record of smoking-related conditions should receive a strong recommendation to quit. In addition, the physicians should elaborate on both the long-term and short-term consequences of smoking (for example, physiological, social, cost), as well as the benefits of quitting. The physician should be sure that the patient understands the harm smoking can cause and how quitting can help. Any misconceptions can be corrected at this time.[35]

Next, the physician should learn whether the patient has attempted to quit before and what type or length of success was achieved. The physician should praise any past efforts and point out that research shows that most ex-smokers attempted to quit several times before succeeding.[36,37]

The fourth step in the documentation is determining the patient's interest in quitting. Surveys indicate that only rarely will a smoker respond that (s)he has no desire to quit.[38] However, if the patient does indicate an unwillingness to stop smoking, the physician should enter in the medical record the patient's reasons for not wanting to quit, reiterate the reasons why the patient should stop, and indicate to the patient that his/her smoking behavior is a primary concern of the physician and it will be addressed at the next visit.

If the patient indicates an interest in quitting, the physician should assess the intensity of the interest in smoking cessation and determine which benefits of quitting smoking are most important to the patient. Alternatively, patients could be asked to complete a printed questionnaire in the waiting room detailing their prospects for quitting (for example, strength of desire to quit, belief regarding chances of success), as well as which benefits of quitting are most and least important to them. Once these steps are completed, the physician should move on to the second component of the basic strategy.

Setting a Date. The physician and patient should agree on a date on which the patient will quit. The physician should make a point of noting this date in the medical record and should indicate that (s)he will

be following up on the patient's success at subsequent visits. This reinforces to the patient the importance that the physician places on quitting smoking. Failure to convey the significance of a regimen usually results in failure to comply.[39]

There are a number of other techniques a physician can use to increase the likelihood that a patient will comply with instructions and be successful in quitting smoking. Tailoring the regimen to fit the patient may improve results. For example, although many researchers recommend quitting "cold turkey," certain patients may not be ready to attempt that step initially. The physician may discuss alternatives such as switching brands, cutting down on the number of cigarettes smoked, or using nicotine gum. There is conflicting evidence as to whether low tar and nicotine cigarettes reduce the risk of cancer,[40] and it is still too early to determine the ultimate value of nicotine gum. However, any positive action toward finally quitting smoking should be beneficial. Whatever method is agreed on, quit date should be established at this time.

"Contracting" with the patient or having the patient "contract" with a friend or family member can be effective in motivating a patient.[41] Contracting involves setting explicit actions to be taken and giving rewards when that behavior is performed. For example, a patient could be encouraged to contract with his/her spouse that if (s)he does not smoke during the day, (s)he does not have to do a particularly disliked chore, or the spouse could agree that money saved by not smoking would be used to purchase a certain item for the "ex-smoker."

Studies have shown that the relationship of the physician to the patient is associated with compliance to instructions. Compliance is positively associated with patients' perceptions that physicians are friendly, interested, respectful, and supportive;[42,43] listen to and understand their concerns;[44] and consider their feelings when recommendations for treatment are made.[45,46] Mutually establishing a quit date, creating a quit strategy that fits the patient's needs, and arranging for support or rewards for success, all aid in increasing the likelihood the patient will follow the physician's instructions.

After agreeing on a quit date, the physician should move on to the next component of the basic strategy, preparing the smoker to be a nonsmoker.

Preparing the Smoker. Preparing the patient to be a nonsmoker involves support, encouragement, and assistance. In addition to the physician/patient relationship described above, social support is the other major factor affecting compliance. Social support means involving the patient's family, friends, or peers. This can be done in a variety of ways such as encouraging the patient to announce to friends and peers his/her intentions to quit or involving the spouse in the physician's discussions with the patient. Involving the spouse is particularly important if (s)he is a smoker. The physician may want to offer counseling but should at least offer advice on how the spouse can be supportive. Research has shown that family behaviors or opinions can facilitate and encourage or inhibit compliance.[47]

Social support can be provided through group programs such as those sponsored by the American Lung Association, the American Cancer Society or Smok-Enders. Additional information on these types of programs in Maryland and guidelines for selection of the appropriate program can be found in the Cox and VanSant article on page 83. Although most former smokers quit smoking on their own without the aid of formal smoking-cessation programs,[48] group encouragement may be helpful to some patients. In addition, some studies have shown improved results with group programs that emphasize maintenance.[49-51]

At this point, the physician should be sure to address the concerns of the patient regarding quitting smoking. These might include the fear of gaining weight or the fact that smoking helps them relax or concentrate better. Physicians might discuss dietary options such as diet diaries or calorie counters, but they should point out that as few as one third of patients who quit may actually gain weight in the initial period after cessation.[52] The physician can counter myths about relaxation or concentration by pointing out that cigarettes are actually stimulants that speed up the heart rate, raise adrenalin levels, and deprive the brain of oxygen.[53]

It should be pointed out that the patient is not giving something up but is gaining control of one area of his/her life.[54] Other benefits of quitting also should be emphasized. For example, nonsmokers generally live seven years longer than smokers,[55] or persons who smoke two packs a day could save $600 to $900 per year on cigarette costs alone.

Confidence should be expressed in the patient's ability to succeed. Acknowledgment may need to be made that it is not an easy task but millions of people have quit, 1.8 million between 1978 and 1980 alone.[56]

Printed materials such as smoking diaries, self-help kits, tips for dealing with stress, dietary advice, or details of smoking hazards and quitting benefits may be useful for physicians to give patients. Printed materials cannot substitute for physician advice but can serve as excellent tools to reinforce physician instructions and to aid patient recall. In fact, research suggests that patients are more likely to quit smoking if the physician combines advice with printed smoking-cessation materials and notice of subsequent follow-up.[57]

After offering encouragement, providing support, informing patients about community programs, correcting misinformation, and distributing printed materials, one other component of the strategy needs to be implemented.

Reinforcement and Monitoring. Since quitting smoking or altering any habit is difficult, reinforcing positive actions and monitoring the patient's progress are crucial. Continued physician interest emphasizes the medical importance of quitting smoking.

Before the patient leaves the physician's office, arrangements for some form of follow-up should be made. An office visit scheduled approximately one month after the established quit date would be ideal, though this may be feasible only if the patient is returning for follow-up of some other problem such as hypertension. Minimally, arrangements should be made for a phone communication sometime after the quit date.

At these subsequent contacts, the patient's progress should be assessed, positive reinforcement provided, and problems addressed. If the patient indicates difficulties such as "I do not know what to do with my hands" or "I cannot get over the need for a cigarette after dinner," the physician should be prepared to offer assurances and constructive suggestions. For example, the physician might advise the patient to play with a paperclip and/or indicate ways to avoid situations in which the desire to smoke is most intense, such as engaging in some sort of activity immediately after dinner that would prohibit smoking. The physician should acknowledge that (s)he is aware of how difficult the undertaking is, that the concerns expressed by the patient are not unusual, and that it is very important for the patient to quit. Comments should be very positive and encouraging. If the patient has relapsed or has smoked a few cigarettes after the quit date, the physician should assure the patient that (s)he has not failed. (S)he has proven (s)he can quit once, now the problem is to quit for good.[58] The patient should be urged not to let a few cigarettes serve as an excuse to begin smoking again. Relapse is an ongoing problem for many people.[59]

Monitoring the patient's smoking status and reinforcing the patient's efforts should continue at every subsequent office visit.

Summary

Smoking cessation is the single most important risk-reduction behavior in regard to both individual and population morbidity and mortality. It is a most cost-effective use of physician time, as the physician can have a significant influence on smoking behavior. The time it takes to read this article belies the small amount of time necessary to encourage a patient to stop smoking. Research has shown that physician contact time of as little as 60 to 120 seconds can have an effect on patient smoking behavior.[60] The approach recommended here, however, involves a counseling protocol of approximately five minutes that is based on very successful research conducted in Maryland and South Carolina.[61] It is not, however, the *amount* of time that is the most important factor but the *quality* of that time.[62–64] This means using available time wisely. The guidelines suggested in this article are not time consuming but do address a number of issues that affect compliance. For example, patients' perceptions as to whether the physician listens to and understands their concerns or considers their feelings when making recommendations for treatment will have impact on the medical outcome.

The information presented in this article is not a guarantee for success. The recommendations, however, are based on work by researchers and physicians in influencing patients to stop smoking.[65–72] The strategy advocated is founded on solid communication principles and health education theory. Research has shown that physicians *can* have a significant influence on smoking behavior.

It is obvious that physicians, in general, recognize smoking as a serious health hazard. Few allow smoking in their waiting rooms, and while 30 percent of physicians were cigarette smokers in 1967, today, less than one physician in five smokes. In fact, 64 percent of all U.S. physicians who were smokers had quit by 1975.[73] Some research has suggested, however, that medical education orients physicians toward treatment and cure rather than prevention. Thus, they may fail to even recognize, much less counsel, large numbers of their patients who smoke. Some physicians may only identify and counsel smokers with symptoms or diseases caused by smoking.[74,75] Other work indicates that the concern for preventive health care is one of the fundamental premises of medicine, at least in family practice.[76] Physicians regularly treat conditions such as hypertension to *prevent* stroke, heart disease, or kidney problems; thus, treating smoking in a precise, methodical manner is no different.[77]

It is understandable, however, that many physicians become disheartened and frustrated when they suggest habit changes with which a patient may not comply.[78–80] Still, using a *conservative* estimate, that 5 percent of patients will heed their physicians' advice and stop smoking, Maryland physicians would be able to influence over 35,000 smokers to quit. The enormous health benefits derived from even this limited success rate are obvious.

The relationship of smoking to lung cancer is clear and definitive. Its connection to other forms of cancer,

as well as other diseases, is rapidly being identified. Smoking causes needless suffering and produces an unnecessary economic burden on society. The potential impact that physicians can have on this serious problem is immense. Though the goal is not easily attainable, the steps for approaching it are relatively easy. Their results can have a more profound effect on the health status of Americans than any treatment or curative procedure.

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HEALTH EDUCATION is a multidimensional process that informs, enables, encourages, and helps people adopt healthful lifestyles and adhere to medical advice.

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- Implement programs for physicians that will help increase patients' adherence to medical advice.
- Develop training sessions for physicians in the techniques of promoting wellness among their patients.
- Offer opportunities for physicians to improve their communication skills.
- Work with other institutions and organizations interested and involved in health education.
- Encourage physicians and organized medicine to actively promote healthy lifestyles and a healthful environment.
- Serve as a resource for information regarding health education activities for physicians.

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Estrogens and Endometrial Cancer

W. B. SCHLAFF MD and N. B. ROSENSHEIN MD

Dr. Schlaff is an Instructor in the Department of Gynecology and Obstetrics, and a Fellow in Reproduction and Endocrinology at the Johns Hopkins Medical Institutions.

Dr. Rosenshein is the Director of the Division of Gynecologic Oncology at the Johns Hopkins Medical Institutions.

Estrogens are a group of related hormones with a similar biologic effect. The identification began with the description of ovaries, first called "female testicles," in the fourth century BC. In the late 1600s, ova were first identified within the ovaries, with ovulation and luteinization described in the eighteenth and nineteenth centuries.[1] In 1896 the hormonal function of the ovaries was demonstrated when Emil Knauer[2] and Joseph Halban[3] independently showed that transplanted ovaries, devoid of nervous connection, prevented "castrate atrophy" of the reproductive tract in laboratory animals. The ovarian substance was called an "internal secretion" and labeled a "hormone" or chemical messenger by Ernest Starling in 1905.[4]

Over the next 25 years, the hormonal contribution of the ovary was characterized. Allen and Doisy, in 1923, identified the source of ovarian hormone by producing full estrus in oophorectomized rats and sexual maturation in newly weaned animals by injection of an extract of ovarian follicular fluid obtained from hogs. They concluded this hormone was produced under the influence of the follicle cells of maturing ova and was not species specific.[5] Frank first describes the female "sex hormone" in the circulation of women in 1925[6] and Loewe and Lange identified the estrogenic hormone in human urine in 1926.[7] In 1927, Aschheim found that even larger quantities were present in the urine during pregnancy.[8] This discovery permitted an adequate supply of hormone to become available for research resulting in a crystallized pure form of estrogen in 1929. During this period, a number of names were suggested for this "sex hormone" but Parkes and Bellerby coined the name "oestrin" in 1926, and this became the most commonly used name.[9] In 1930, G.F. Marrian discovered that "oestrin" was not a single hormone by identifying several different estrogenic substances in the urine of pregnant women.[10,11] Over the next six years, estrone, estradiol, and estriol were differentiated. In 1938 Dodds[12] developed diethylstilbestrol, the first synthetic, nonsteroidal estrogenic compound.

The developing field of steroid biochemistry permitted the investigation of hormones for contraceptive purposes. In the early 1950s, Pincus demonstrated ovulation inhibition by synthetic progestins.[13] This led to a large field test in Puerto Rico in 1956 that proved the effectiveness of synthetic steroid hormones in contraception. The first oral contraceptives were marketed in this country in 1960, and over the past two decades, oral contraceptives have continued to evolve using decreasing quantities of estrogen. Their widespread use has had significant implications in the health care of women in subsequent years.

Pharmacology

Estrogens are 18-carbon steroids produced in the ovaries, placenta and peripheral tissues by aromatization of the A-ring of the androgens, androstenedione and testosterone. Estradiol is the most potent of naturally occurring estrogens, but there is conversion to the other estrogens, estriol and estrone (Figure 1).

Estrogens are rapidly absorbed through skin, mucous membranes, and the gastrointestinal tract. In the plasma, estrogens are almost completely bound to sex-hormone-binding globulin and albumin. Effects occur only when estrogen is in the free form and only in tissues that possess estrogen receptors. The limited oral effectiveness of naturally occurring estrogens is due to the rapid absorption and metabolic transformation in the liver. The estrogens are metabolized by degradation to nonestrogenic substances, to less active estrogens, and by conjugation to sulfates and glucuronates for renal excretion.[14] Thus, natural estrogens must be modified to be orally active. In 1938, it was discovered that

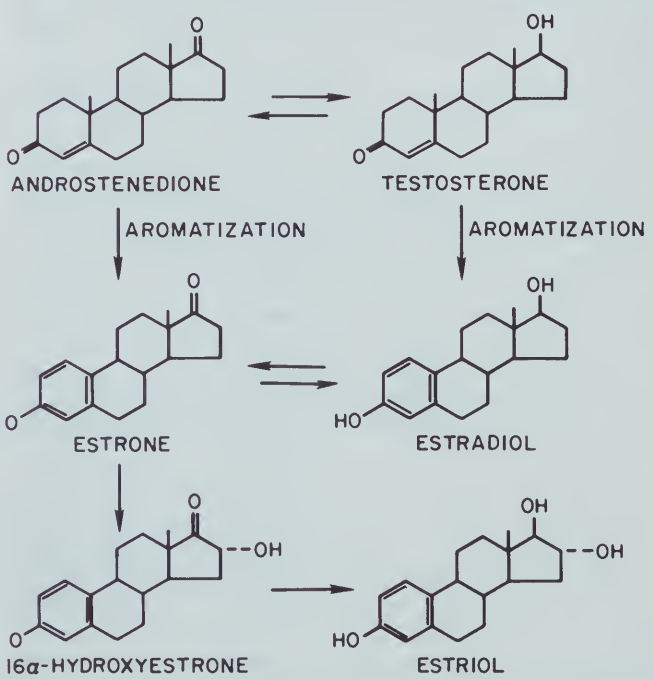


Figure 1. Estrogen metabolism, and interconversion between estrone, estradiol and estriol

adding an ethinyl group at carbon-17 would allow the molecule to avoid rapid metabolic transformation. The resulting compound was ethinyl estradiol, the most common component of oral contraceptives. Mestranol, another synthetic estrogen, must be metabolized to ethinyl estradiol to become active (Figure 2).

The vaginal route of estrogen administration permits efficient absorption and physiologic plasma levels to be reached. The systemic estrogen effect depends on the specific estrogen preparation used as well as the dosage. Vaginal estradiol cream results in rapid high levels of estradiol with low levels of estrone, while conjugated estrogen given in the same manner produces much lower levels of estradiol and higher levels of estrone.[15,16]

Estrogen action is mediated via estrogen receptors. First described in the 1960s, these receptors are a heterogeneous group of intracellular macromolecules that are essential for the expression of estrogen-induced events. The generally accepted scheme of estrogen receptor interaction is presented in Figure 3. Lipophilic steroid hormone passively enters the cell where it is bound to a high affinity cytosol receptor. This receptor undergoes transformation from an inactive complex to an active one and is translocated to the nucleus. Once translocated, the steroid receptor complex binds to acceptor sites on the nuclear chromatin producing conformational changes in the chromatin structure and exposing additional DNA templates for transcription. RNA polymerase activity follows and results in increased transcription and, ultimately, protein production.[17-20]

These estrogen-induced effects take place quickly. Translocation of the cytosol-bound hormone receptor complex occurs within ten minutes of estrogen injection. RNA polymerase activity is increased within 15 to 30 minutes, and new proteins are secreted within an hour. There are both short-term and long-term effects of estrogen, which are summarized by Katzenellenbogen in Figure 4, next page. Within one hour of treatment, several metabolic changes occur including increased glucose metabolism, phospholipid synthesis, and DNA template capacity. Increases in net RNA and protein occur in 6 to 18 hours. At 18 to 24 hours, DNA synthesis increases and cell division occurs.[21]

The relative potency of different estrogens is the result of their varying effects on estrogen receptors. Four different types of receptors are commonly described, two each in the cytosol and nucleus. Cytosol Type I are the classical estrogen receptors and when translocated to the nucleus are called Nuclear Type I. Nuclear Type I receptors mediate the early phases of estrogen activity as outlined above. Cytosol Type II receptors do not translocate and are believed to function in concentrating estrogen in the cellular environs. Nu-

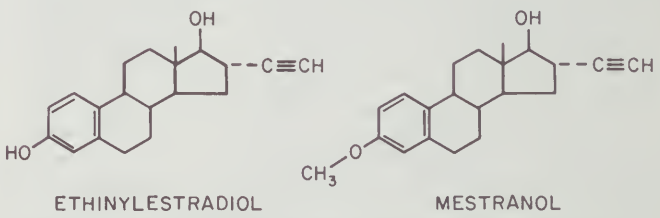


Figure 2. The structure of the common estrogen in the combination oral contraceptive

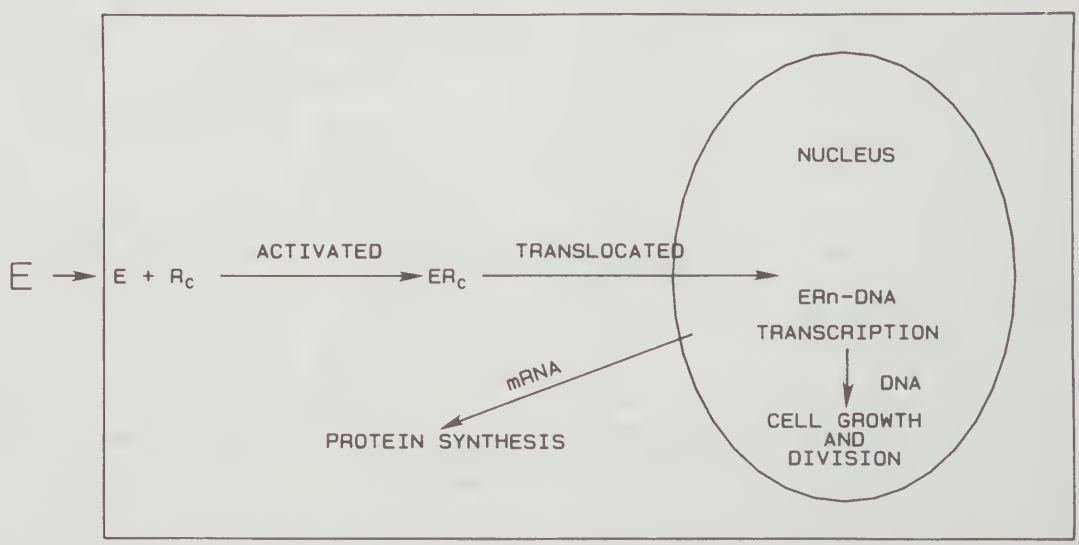


Figure 3. Diagram of estrogen-estrogen receptor interaction in the cytoplasm and nucleus

clear Type II sites are confined to the nucleus and are not translocated from the cytosol. They likely are induced by prolonged stimulation of Nuclear Type I sites. It seems clear that the long-term growth and replication induced by estrogen are almost exclusively mediated by these Type II sites.

An injection of either estradiol or estriol will increase Nuclear Type I receptors within minutes. Estradiol stimulates these sites for four to six hours while estriol will cause their retention for a far shorter time. Furthermore, estradiol injection will result in induction of Nuclear Type II receptors and promote true growth, while estriol will produce no such effects. It is likely that the mechanism of Type II receptor development may depend on conformational changes induced by prolonged exposure to Type I receptor complexes.[22]

These pathways can be modified by dose, duration, and other mediators. As an example, estriol can stimulate induction of Type II nuclear receptors in certain settings, such as when given in a continuous fashion as opposed to a single injected bolus. This can be accomplished using subcutaneous pellets in laboratory animals and is consistent with clinical findings of unopposed estrogen in chronically anovulatory women.

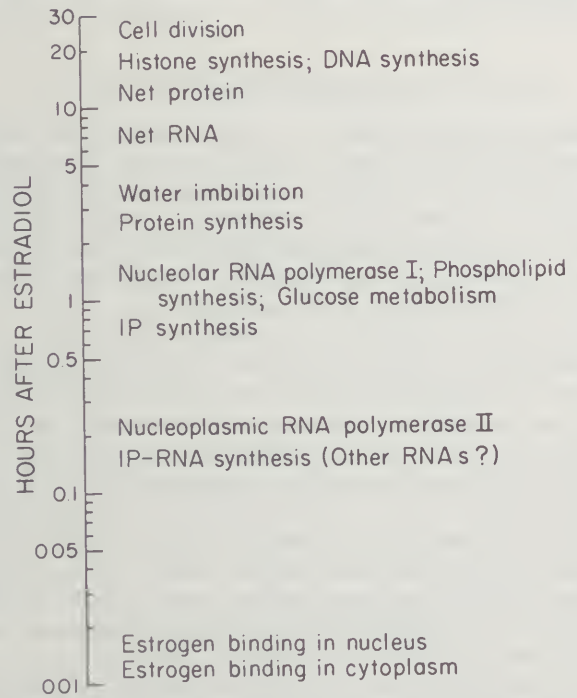


Figure 4. Temporal sequence of events after in vivo injection of estradiol-17β Time (hours) is on a logarithmic scale (0.01 hr = 0.6 min)

Other hormones such as dexamethasone and progesterone can modify receptor development and thus affect estrogen actions.

While target tissues will demonstrate normal response, the system may become dysfunctional as malignant transformation occurs. In any given tumor, a spectrum of cell lines exists with some cells retaining their ability to produce receptors and others losing this capacity. Hormonal responsiveness of tumors is related to the mix of receptor function of the various cell lines.

Estrogens and Cancer

Estrogens are used typically in the postmenopausal population to treat the 75 to 85 percent of those women who are symptomatic secondary to estrogen deficiency or enter a program to retard the development of osteoporosis.[23] The benefits of estrogen replacement therapy should be discussed in the context of its risks. The risk to be discussed is that of the relationship of estrogens to cancer.

There are experimental findings to indicate that estrogens are not direct carcinogens but rather render the hormone response cells more susceptible to carcinogens.[24] If cancer occurs, it is thought to occur through a process of initiation and then promotion. In this model, estrogens act as promoters of a separate initiating event.[25] The two estrogen-cancer relationships that are of most concern to the physician are those of breast and endometrial cancer.

Since the introduction of estrogen therapy into the United States in the 1930s it has been suspected of contributing to the development of endometrial carcinoma. This is based on estrogen-producing normal growth of the endometrium during each menstrual cycle and continuous estrogenic stimulation of the endometrial tissue possibly inducing neoplasia or, at least, hyperplasia. It is generally accepted that long-term stimulation of the endometrium by unopposed estrogens leads to hyperplasia (excessive tissue growth due to an increase in the number of cells), a condition that may be a precursor to endometrial cancer, but this is by no means proved. The first report in the medical literature linking the long-term use of estrogen to the development of endometrial cancer was published by Fremont-Smith *et al.* in 1946.[26]

There is substantial information from epidemiologic studies that prolonged unopposed estrogen replacement therapy in the menopause is associated with an increased risk of endometrial cancer.[27] The degree of risk is associated with duration of estrogen use. The longer the period of estrogen stimulation, the greater is the chance a carcinogenic event will occur.[28] The increased risk of endometrial cancer attributable to estrogen ad-

ministration can be decreased by the use of progestins and prescribing estrogens for short periods of time at a low dose.[29–30] Progestins act to reduce the estrogen stimulation of the endometrium by decreasing the number of estrogen receptors in the endometrium, shifting the metabolism from estradiol to estrone, a less potent estrogen, and increasing metabolic inactivation of estrogen by sulfurylation.[31–33] There is clinical evidence that periodic administration of a progestin will protect postmenopausal women receiving estrogen replacement therapy from developing endometrial cancer.[34] Since the risk of endometrial cancer can be averted by the use of a progestogen, it should be part of the therapeutic plan to include a progestogen as part of estrogen replacement therapy.

The association of estrogen and breast cancer is not as clear as that of endometrial cancer. A concern about the effect of estrogens on the breast is based on epidemiologic evidence that prolonged estrogen stimulation of the breast parenchyma, in the form of early menarche and late menopause, is associated with higher breast cancer rates.[35] Stimulation of breast tissue by exogenous estrogens in postmenopausal women has been demonstrated by mammograms indicating cystic or dysplastic changes.[36] The response of breast cancer to oophorectomy or antiestrogen therapy indicates that estrogens can have a role in stimulating or maintaining breast cancer. A clear association between postmenopausal estrogen replacement therapy and an increased risk of breast cancer cannot be demonstrated at this time. Numerous studies have provided conflicting data. If an effect of estrogens on breast tissue to increase risk occurs, it is not a strong one. The subgroups of estrogen users probably at increased risk are those with prolonged duration of use, higher dose, and longer time since first use.[37–39] The longer time since first use is an expression of longer latency period such as age at menarche and age at first live birth. As with endometrial cancer, the addition of a progestogen may provide protection from the additional risk of unopposed estrogen.[40]

Many authors have studied the relationship between estrogen use and the development of ovarian carcinoma. The initial impetus for these investigations was the finding of a high frequency of ovarian tumors after administration of diethylstilbestrol to dogs. Initially, Hoover uncovered an increase in risk for ovarian cancer among women who had used exogenous estrogens.[41] In this study, 908 women who had received Premarin® alone or in combination with other estrogens for postmenopausal symptoms were followed for a maximum of 30 years. No statistically significant increase in risk for ovarian cancer was detected. When the analysis was restricted to the 21 women who had used Premarin® and diethylstilbestrol, an increased relative risk was observed that was statistically significant. Bibbo observed a nonstatistically significant increase in the incidence of ovarian cancer in 693 women who had received diethylstilbestrol during a clinical trial designed to assess its effectiveness in preserving pregnancies.[42] Cramer noted a statistically significant increase in the incidence of endometrioid and clear-cell cancers during the 1970s and suggested that this increase was due to either an increase in the use of exogenous estrogens during this time period or an artifactual increase in the diagnosis of endometroid and clear-cell cancers as histologic entities during the same time.[43] In a case-control study using 17 endometroid ovarian carcinomas, an association was detected between the consumption of exogenous estrogens and the development of endometrioid cancer that was statistically significant.[44] When other types of epithelial ovarian cancer were analyzed, no other positive associations were observed. A number of studies were not able to detect an increased risk for ovarian cancer with exogenous estrogen use. Women participating in a follow-up study of chronic anovulation, where there was significant exposure to unopposed natural estrogen, were found not to be at higher risk for ovarian cancer.[45] If an increased risk for ovarian cancer occurs with the use of estrogen replacement therapy, it is probably with the specific histologic type of endometrioid carcinoma.

Oral Contraceptives and Cancer

Most oral contraceptives contain an estrogen and a progestogen given together for 21 days of the month. Introduced in the early 1960s, the oral contraceptives have been investigated extensively. Studies indicate that combination oral contraceptives may protect against certain types of cancer; other reports suggest they may take part in carcinogenesis.

The Food and Drug Administration (FDA) concluded there appears to be no increased risk of breast cancer in oral-contraceptive users or any subgroup of users, or with any particular type of oral contraceptive.[46] In addition, benign breast disease (which has been considered a risk factor for the development of breast cancer) is decreased in women taking combined oral contraceptives.[47] If an individual develops benign breast disease while taking oral contraceptives, she may be at increased risk for developing breast cancer.[48] Oral contraceptive users who later develop breast cancer may have less advanced tumors at the time of diagnosis.

The relationship of oral contraceptives to endometrial cancer is interesting. The sequential oral contraceptive, which had 14 days of a large dose of estrogen followed by six days of a relatively weak progestogen,

were associated with an increased risk for developing endometrial cancer and were removed from the American market.[49] In contrast, combination oral contraceptives in several studies have been shown to exert a protective effect for the development of endometrial cancer.[50]

Oral contraceptives in case-control studies have been associated consistently with a decreased risk for ovarian cancer. Certain studies have indicated that there is a nonstatistically significant decrease in risk with increasing duration of oral contraceptive use.[51–54] The mechanism of the protective effect of the oral contraceptives is thought to be on the basis of a cessation of ovulation during its use, as it has been observed that "incessant ovulation" is associated with increased risk.

The relationship of oral contraceptives to cervical cancer is a complex issue as the data may be confounded by the strongest risk for preinvasive and invasive cervical cancer: sexual activity. No consensus opinion has emerged between the relationships of oral contraceptives and cervical cancer due to the inability to control for the confounding variable of sexual activity. The FDA is planning to revise the oral contraceptive labeling to include a warning that oral contraceptive use may be associated with an increased incidence of cervical carcinoma.[55] Patients using oral contraceptives should be monitored carefully by physical examination and cervical cytology.

Conclusion

The facts that there are 40 million postmenopausal women who may potentially benefit from estrogen replacement therapy and that a large cohort of women in the reproductive years are exposed to oral contraceptives makes the issue of whether estrogens are carcinogenic important to all physicians.

It is believed that estrogens are not carcinogenic but are promoters in the process of malignancy. The organs at risk for promotion are those that are hormonally responsive: breast, endometrium, and ovary.

Data appear to indicate that the association between estrogen-replacement therapy in the postmenopausal woman and breast cancer is unclear. The risk of endometrial cancer is increased with unopposed estrogen but is reduced with cyclic progestogen therapy. Ovarian cancer and its relationship to estrogen therapy has not been clarified, but if an increased risk occurs it is with the subset of ovarian cancers similar to endometrial cancer, the endometrioid tumors.

Oral contraceptives are protective against endometrial and ovarian cancer and have no increased risk for the development of breast cancer. There is a concern about oral contraceptives and increased risk for cervical cancer, which requires further study.

Estrogens have documented benefits for patients as treatment for menopausal symptoms and as part of combination oral contraceptives. The decision for their use should be an individual one between physician and patient.

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Public Perception of Cancer Risk and Prevention: Implications for Physicians

JOY WILSON MPH, ROSE MARY ROMANO MA, and JUDITH STEIN MA

Wilson has served as a Public Affairs Specialist with the Office of Cancer Communications, National Cancer Institute.

Romano is the Chief, Information Projects Branch, Office of Cancer Communications, National Cancer Institute.

Stein is a Project Officer, Cancer Communications Network, National Cancer Institute.

Despite advances in its treatment and cure, cancer is associated with fear and fatalism. Over the past ten years, scientists have made advances in the early detection, treatment, and cure of many forms of cancer. The current five-year relative survival rate for patients is 48 percent, making cancer the most curable chronic disease. However, all the information about progress against cancer means very little to a person who has lost a family member to cancer or to one who believes "there is little I can do about it."

The "war on cancer" focused attention on cure. But, as Butler and Paisley note, "There was a time when it seemed that medical advances would ease our concern about cancer.... But, the day of the miracle drug is years away. In the meantime, many are recognizing that lives could be saved if the public would utilize what is already known about cancer prevention and cure."[1]

What does the public believe about cancer prevention and cure? Results from a nationwide survey conducted by the National Cancer Institute indicate that the public's view of cancer is confused and skeptical. Myths and misperceptions exist, and people feel there is little they can do to reduce their risk of developing cancer. Many believe that "everything causes cancer" and "there isn't much a person can do to prevent cancer."[2]

Communicating accurate health information is difficult because the subjects are complex and technical. Information may be controversial, inconclusive, and subject to change as new research findings develop. Cancer arouses fear, and responses to information can be emotional. As a result, inappropriate messages can alienate or misdirect the public. This presents many obstacles for the physicians and health professionals trying to help their patients evaluate information about cancer.

In response to the problems posed by the public's limited understanding of cancer, the National Cancer Institute (NCI) initiated a major national education program: the Cancer Prevention Awareness Program. Its goal is to improve public knowledge and attitudes about cancer prevention and to encourage individuals to adopt healthier "life-styles."

During the first phase of the program, mass media messages were developed to increase public knowledge about cancer prevention. During the second phase, program emphasis will shift to target populations at high risk, for example, heavy smokers. A major part of the program is aimed at physicians and other health professionals to help them understand patients' attitudes about cancer and how those attitudes affect understanding and acceptance of health information.

Before the Cancer Prevention Awareness Program was launched, the Office of Cancer Communications attempted to determine:

- What are the public's perceptions about cancer?
- What differences exist among population subgroups?
- How do people receive information about cancer?
- Who are regarded as credible sources of information about cancer?

We review the findings from the NCI survey on these questions, discuss effective channels of communication, and explain how physicians can help motivate their patients to reduce their cancer risks.

Public Views of Cancer

In developing the basic content of the prevention messages, NCI conducted both qualitative and quantitative research to examine:

- Attitudes and behavior about health risks and prevention
- Perceptions of disease susceptibility
- Current attitudes, beliefs, and behavior patterns relating to cancer

Focus groups (also called exploratory group sessions) are a way to gain insight into target audience perceptions, beliefs, and language in the early stages of health communication development. Thirteen were conducted between December 1982 and January 1983. They included both male and female Hispanics, blacks, high-risk blue-collar workers, and the elderly. The sessions yielded four types of attitudes: the fatalist, the diligent, the avoider, and the oblivious.

The *fatalists* believe there is nothing they can do about cancer. Therefore, they believe there is no need to change their daily activities. "I try not to think about it," said one elderly man. "I can't worry about it day after day." Another man said, "Life is a lottery, and cancer is one of the numbers." Those falling into this fatalist category included elderly men and women, high-risk blue-collar workers, and black men and women.

The second group, the *diligents*, believe they have control over their destiny and there are things they can do to prevent cancer. They are interested in obtaining information. They read, watch TV, and talk to friends about cancer. This group consists mostly of women from a variety of educational and socioeconomic backgrounds. Although they are concerned about their own

health and take preventive steps (for example, watch their diet, perform breast self-exams, get regular PAPs), their major worry is their family, "I'd rather have cancer myself than see my children suffer with it," said one woman. "I know I can deal with it."

The *avoiders* avoid information. They are not informed and do not visit physicians regularly. They view cancer as a dreaded disease, ghastly and beyond imagination. This group is chiefly men of varying levels of education and economic status. Unlike the diligents, they fear more for themselves than for others.

The *oblivious* think they are immortal. They are healthy, feel good, and do not think there is anything they need to do about cancer. This group is mostly young people, and to some extent, black women. While the fatalists do not think about cancer because there is nothing they can do about it, the oblivious do not think about it because they think there is nothing they need to do about it.[3]

To help further in planning a cancer prevention effort, a survey population consisting of a national probability sample of 1,876 was interviewed by telephone during the week of June 20, 1983. Responses to the survey indicated that the public's view of cancer is confused and skeptical. About half the respondents believed that everything causes cancer and that there was not much a person can do to prevent cancer. Despite their beliefs, respondents identified tobacco, sunshine, and x-rays as cancer risks. However, almost half said bumps and bruises could increase the chances of getting cancer. Other popular cancer myths expressed in the interviews were that cancer was contagious, hereditary, and spread by surgery. Less educated and older respondents tended to have more misconceptions about cancer risks and prevention. Most often mentioned actions a person can take to reduce cancer risk included cutting down or stopping smoking and changes in food choices or diet habits.

How People Get Health Information

Mass media and interpersonal communication provide the main sources of information about cancer. The most frequently reported sources of information about cancer prevention were magazines (63.6 percent), newspapers (60 percent), and television (58.3 percent). Many interviewees said information they received about cancer in the news was contradictory and the media sensationalized stories to increase sales and ratings. Information from family members and friends accounted for 42.4 percent and 38.7 percent, respectively, of cancer prevention knowledge.

Physicians are cited as one of the most reliable and credible sources of information.[4–6] The majority of patients say they would be strongly influenced to adopt or change a certain behavior if recommended by a physician.[7–9] When asked how likely they would be to follow a physician's advice about ways to reduce their chances of getting cancer, nearly 91 percent said they would be likely to do so. People over age 60 said they were more likely to follow a physician's advice than were younger people. However, many said their physicians did not make recommendations about their behavior, including smoking, drinking, and diet habits. When asked if they ever had talked to a physician about ways to reduce their chances of getting cancer, nearly 86 percent said "no," and only 14 percent said "yes." Many patients have questions for their physicians but are hesitant to ask them because they are afraid to reveal their ignorance or are reluctant to take up too much of the physician's time.[10] (Conversely, physicians get frustrated when they suggest "life-style" changes and patients do not follow their recommendations.[11–13])

Who Asks for Information on Cancer Prevention?

A source of information on cancer prevention is the Cancer Information Service (CIS), a telephone service developed and funded by NCI. The CIS program is described in another article in this journal entitled "Resources: Cancer Prevention" (page 83).

CIS has been the point of contact for the public throughout the Cancer Prevention Awareness Program. The toll-free CIS telephone number (1-800-4-CANCER) is provided in all campaign materials and public service announcements (PSAs) as a place to call for additional information and publications on cancer prevention.

Promotion of the CIS number has led to dramatic increases in the number of calls for information on cancer prevention. Calls for the three months of December 1983 through February 1984 totaled 468. At this time, two 30-second TV PSAs were distributed nationally. In March, calls to the CIS on cancer prevention skyrocketed to 5,994 and peaked in April at 12,384. As late as June 1984, almost 8,000 calls on prevention were received by CIS offices in response to the PSAs.

A standardized form in use in all CIS offices allows for concise documentation of each inquiry to CIS. Information such as type of user, nature of inquiry, and user demographics is collected for each caller. Data on 35,486 callers were analyzed and help provide a profile of those callers requesting information on cancer prevention.

Over 90 percent of prevention callers are members of the concerned general public (not cancer patients, their families, symptomatic individuals, or others). Many

questions are on issues related to diet and nutrition, and smoking. Only 6 percent of the calls related to a specific cancer site. Of those, many questions concerned breast, colon, lung, prostate, and skin cancer. Since the public service announcements promoted a specific NCI publication, over 92 percent of prevention callers requested it be mailed to them.

Sixty-five percent of prevention callers are women, a slightly lower proportion than CIS callers on all topics combined. Over 46 percent of prevention callers are between 20 and 39 years old. Another 45 percent are age 40 or above. Over 8 percent of prevention callers are 19 years old or younger.

Over 87 percent of these prevention callers have at least a high school education; 30 percent have at least a college degree. Eighty-nine percent of prevention callers are white, 7 percent are black, and 2.3 percent are Hispanic.

The largest single proportion of prevention callers (25 percent) were in the Southeastern states, followed by the Great Lakes region. The fewest inquiries about prevention were from callers in the Rocky Mountain states, the far West, and New England.

This analysis reveals that people interested in cancer prevention represent a broad cross-section of the public. Their ages range from the very young to the very old. They are generally well educated. Callers' response to the offer of a free pamphlet on cancer prevention reflects their high receptivity to information on the topic. As the cancer prevention awareness campaign progresses, we continue to monitor the level of public response and nature of the public's inquiries on the subject.

Implications for Physicians

Although physicians may believe that people do not follow their advice, many studies indicate that physicians underestimate their impact on patients and may need to reassess what are reasonable success rates.[14,15] The National Institutes of Health notes, for example, that if U.S. physicians persuaded 5 percent of their smoking patients to quit, the result would be about two million ex-smokers.[16]

It is important for physicians to encourage questions and to provide accurate information about the controversial issues associated with cancer. Many people are interested in the link between diet and cancer, for example. McGinnis notes that people are trying to improve their eating habits, but they are confused by the mixed messages and incomplete information they receive.[17] People listen to recommendations by health professionals to eat foods high in fiber, but the general public may not know what fiber is or what foods contain it. Brammer and DeFelice note that the public seeks answers regarding the diet and cancer link and will look to anyone regardless of their qualifications, willing to provide answers.[18] It is important that physicians be willing to answer questions about cancer risk and prevention and to understand the patients' perceptions about cancer. People's attitudes and perceptions influence the way they understand health information and ultimately how they act on it. Therefore, in providing information to patients, it is important that physicians consider the patients' perceptions of susceptibility, levels of fear, and other attitudes that affect the overall acceptance of information.

NCI hopes to work with physicians to develop effective patient educational programs to assist in informing the public about cancer risk and prevention. One such program is the "Quit for Good"* smoking kit, which contains information to assist health professionals in helping their smoking patients quit. It provides a guide for physicians for addressing the major questions patients have about smoking. NCI plans to work with physicians and other health professionals to target high-risk groups, develop effective education programs, implement these programs, and then evaluate the results.

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* The kit of smoking cessation materials can be ordered free of charge by writing to: Quit for Good Kit, National Cancer Institute, Bldg. 31, Room 10A18, Bethesda, MD 20205.

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Cancer Risk Reduction: A Focus on Physicians

CARMINE M. VALENTE PhD and JANET L. CAMPBELL MS

Carmine M. Valente is Executive Director and Janet L. Campbell is Health Educator of the Center for Health Education, Inc.

The National Cancer Institute has identified seven risk factors related to cancer: tobacco, alcohol, diet, radiation, estrogens, occupational exposures, and viruses. Although estimates vary on the relative importance of these factors scientists agree that cancer is largely an avoidable disease when adequate preventive measures are taken.[1] Since many of these risk factors are associated with personal behaviors, clearly individuals need to make greater efforts to reduce their own cancer risk; physicians are in a unique position to influence patients to make these changes. Physicians are cited by the public as the single best, most reliable, and credible source of health information.[2,3]

The Center for Health Education, Inc. (CHE) and the University of Maryland, Department of Family Medicine conducted a survey with 1,040 Maryland physicians. To obtain more specific information regarding the practices of Maryland physicians in cancer risk reduction, the obstacles they encounter in addressing this topic, the techniques they use to support their efforts, and the types of assistance they deem would be helpful, CHE conducted a series of in-depth focus-group discussions with 27 primary care physicians. (A focus group is a structured meeting designed to elicit beliefs about a particular topic.) The approach is flexible, providing latitude for spontaneity and candor and encouraging individual participation, as shown by this outline:

Focus Group Outline

1. In past research, physicians reported that part of their responsibility or role is to try to modify people's behavior in an effort to minimize risk factors. What cancer prevention topics do you normally address with patients? (and when and how do you bring them up?)

   Do you talk about

smoking	viruses
x-rays	diet
alcohol	occupational exposures
estrogens	other
sunlight	

   - addressed at every meeting
   - only if patient has related problem (e.g., smoking/bronchitis, sunlight/sunburn)
   - only if patient has questions
   - if time permits
   - other

2. The literature cites various obstacles that hinder or even prohibit physicians from talking with their patients about cancer prevention or other health promotion topics. From your experience, what are some of the barriers or obstacles you faced in addressing these topics? (and do you have any suggestions on how to eliminate or overcome these obstacles?) For example
   - lack of time
   - sensitive subject
   - inappropriate topic
   - controversial topic
   - lack of information about the topic
   - no reimbursement for time spent
   - limited printed or audiovisual materials for patients
   - other
3. Are there any strategies or techniques you use in working with particularly difficult patients in the area of cancer prevention, e.g., heavy, long-time smokers?
4. Would any of the following forms of assistance be helpful to you in your patient-education efforts regarding cancer risk reduction?
   - literature on cancer prevention topics for distribution to patients
   - preprinted risk factor questionnaires to complement or supplement medical histories
   - literature on cancer prevention resources in the community (e.g., stop-smoking programs, nutritional assistance programs)
   - videotapes or other audiovisual programs for use in waiting rooms
   - continuing medical education in specific cancer prevention subject (e.g., nutrition and alcohol). If not, why not?
   - continuing medical education in communication and/or behavioral modification skills. If not, why not?
5. What influences you to read, attend, or listen to information from various sources? (and what causes you to disregard various sources of information?)
   - reimbursement for time spent
   - credibility (JAMA, etc.)
   - CME credits
   - appeal from a respected group (AMA, Med-Chi, etc.)
   - support by local physicians (your colleagues)
   - endorsement by a national figure
   - stamp of approval by government organization (NCI, NIH, etc.)
   - availability (detail men, direct mail)
   - other
6. What are the best means to educate and/or provide information to physicians?
   - conferences
   - CME courses
   - journal articles

Results

Cancer Prevention Topics Addressed Physicians were asked which cancer prevention topics they normally addressed and how and when the topic was broached. Though answers varied, smoking was by far the major issue addressed on a regular basis, and it was almost always physician initiated. Though other cancer prevention topics were addressed regularly during annual physicals or at initial contacts between patients and physicians, smoking was mentioned much more often. This seemed to be due to the definitive link between smoking and both cancer and heart disease. Some physicians announced that they discussed smoking whenever they could, because "many people do not come in for annual physicals, particularly those under 40, but only when they have a symptom such as a sore throat."

A number of physicians stated it was important that physicians set an example by not smoking themselves. Most indicated they did not allow smoking in their offices, and they had no-smoking signs and antismoking literature in their waiting rooms.

Secondary prevention (that is, early diagnosis) in the form of breast and pelvic examinations also was discussed. Obstetricians/gynecologists think women expected these examinations when they came for a routine visit. Many nonobstetricians/-gynecologists also taught women breast self-examination, as well as encouraged their female patients to see a gynecologist for a PAP smear.

Proctoscopy, rectal, and stool examinations also were a major topic of discussion among "focus-group" physicians, though practices and behaviors differed.

Primary prevention topics beside smoking cessation were touched on somewhat less often. Questions about diet or occupational exposures and/or warnings about x-rays or sun exposure were not standard discussion items of all physicians in the focus groups. Problems that hinder or impede physicians from regularly addressing these topics are described next.

Obstacles and Barriers From responses to the question "What cancer prevention topics do you normally address?" it is clear that cancer prevention for physicians is generally synonomous with smoking cessation and early detection of the disease. When probed, participants elaborated on issues they thought made it difficult to address other cancer risk-reduction topics.

Lack of adequate scientific information was a significant problem for many. They wanted to know what substances or behaviors actually have been identified as having a causal or protective effect with regard to cancer. They pointed out that prevention recommendations from various authoritative groups such as the American Cancer Society and the American College of Gynecologists and Obstetricians were often at odds with one another. Too, physicians believed that patients thought everything caused cancer, and they did not have scientific information to counteract it. Misinformation or confusing information in the media was viewed as a problem. Physicians noted the difficulty of correcting patients' misconceptions.

A number of physicians elaborated on the difficulty of working with patients with varying health beliefs. It was pointed out that it was difficult to talk about long-range prevention when many individuals are faced with more immediate concerns, for example, housing, clothing, or the next meal. "With current difficulties, preventing cancer 30 years down the road is not going to be a number one priority." Likewise, the word "cancer" was thought to arouse an intense fear in some patients. As one physician stated, "They are afraid of cancer and reluctant to discuss it. They think you have found something but do not want to tell them about it." Physicians pointed out that some patients want and expect annual physicals, screening tests, and health promotion advice. Other patients are more fatalistic: "If something is going to happen, it will happen, and I will get it treated then." They are not interested in prevention or early detection.

Communication and literacy problems were viewed as obstacles. For example, some physicians stated they would carefully explain something such as breast self-examination using models and printed materials, but afterward, patients would indicate they did not know what they should be looking for. Similarly, physicians pointed out the difficulty of working with those who have some educational limitations such as school dropouts or those with limited English-speaking ability. These patients often do not have even basic health knowledge and may be unable to read or understand educational leaflets.

While some writers have suggested that the greed for profit has become the motivating force for physicians,[4] the issue of reimbursement for time spent with patients on health promotion was not a major concern and was not viewed as a major barrier for most physicians in the focus groups. Indeed, most physicians pointed out "it is part of the job" and "if you are seeing a patient for an annual visit, you definitely should address the issue, as well as provide all secondary prevention services."

Finally, time constraints were a problem for a few physicians. The hustle and bustle of episodic care, the difficulty of "squeezing a lot in a single visit because you do not think you will ever see the patient again," and being called away to the hospital for births or emergencies, were mentioned as limiting the time available for health-promotion activities.

Strategies and Techniques Acknowledging that barriers and obstacles to engaging in cancer prevention activities exist, we queried physicians as to strategies or techniques they used to support their efforts.

Almost all physicians kept their waiting rooms well stocked with patient education literature. Physicians pointed out that literature is only useful if properly explained. The physician needs to invest importance in the leaflet by talking about it and pointing to it. Many also used slide tape or videotape presentations, particularly on smoking and breast self-examination. Some used models such as "Betsy Breast" to aid in education.

Patient interest and knowledge often were seen as related to media attention to an issue. Physicians mentioned a variety of topics (colorectal cancer screening, asbestosis, mammography) that had been given a lot of coverage by television, radio, newspapers, and magazines for a short time. They thought they could capitalize on this information in educating patients, but the information needed to be reinforced by the media.

Patients who fell into the at-risk category were believed to be the easiest to influence with regard to early detection and prevention. Young women were specifically mentioned as those with whom physicians could introduce the idea of yearly PAP smears and regular breast self-examination. The use of a risk questionnaire or screening checklist in working with high-risk patients was mentioned by several physicians. Other techniques mentioned by physicians included using themselves as examples (for example, if they were ex-smokers); addressing patient's self-image (smoking causes skin wrinkles); putting all instructions on a prescription pad to emphasize their medical importance; having the nurse reinforce all instructions before the patient leaves; discussing relevant family history (talk about a relative with breast cancer); and using medical tests to point out damage and show improvements as the result of behavior change (for example, pulmonary function tests for smokers).

Helpful Forms of Assistance To counteract some of the barriers to cancer risk-reduction education and to aid physicians in their current efforts, physicians were asked what forms of assistance would be most helpful to them.

Patient literature on cancer prevention elicited a variety of comments from physicians. Some believed plenty of publications were available. Others suggested pamphlets should be shorter and simpler. Physicians mentioned wanting a simple brochure detailing cancer risk factors that they could go over with the patient in less than five minutes and then give to the patient to take home. A risk-factor questionnaire to complement or supplement medical histories would be useful to some physicians, though there were some concerns about literacy.

A majority of focus group physicians wanted courses, literature, or other forms of education that would specifically enhance their ability as health care providers. They were not particularly interested in "academic or esoteric topics." Due to time demands, physicians wanted information or skills that could be put to use immediately in their practices. Almost all indicated they would like specific information as to which factors, habits, and/or "life-styles" have a scientifically proved relationship with cancer. In addition to explicit information about primary prevention, physicians were very interested in details regarding secondary prevention or early detection activities, indicating that small workshops were the best way to provide this information.

Finally, consumer education, media attention, and the active involvement of industry working toward reducing cancer risk were mentioned as being valuable to physicians in their educational endeavors.

Influences on Physicians More courses, programs, publications, and the like are offered to physicians than they could ever deal with. Physicians were asked what influenced them to attend an individual program, read some material, or listen to particular information. Of major concern was whether the material or course offered *practical, precise* information. Who sponsored the session or who produced particular materials was also of interest to many. High priority was given to those programs or materials provided under the rubric of medicine (for example, endorsed by the Medical Association or National Institutes of Health).

The size of a program was also a concern. Small groups were considered to be the most valuable. The opportunity to interact with colleagues and to discuss experiences with other physicians was of prime importance. While recognizing that this was an expensive method of education, it was thought to be well worth it.

Convenience, including geographical location and offering programs at a variety of times, was also considered extremely important.

Discussion

The results of the group discussions indicate the interest and involvement of Maryland physicians in cancer risk reduction. The physicians' comments also point out the need to clarify what substances and behaviors actually have a causal or protective effect with regard to cancer.

Focus-group participants also stressed that physician-oriented programs should offer practical informa-

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tion applicable to and useful for office-based physicians. They indicated that courses should be small, convenient, and endorsed by organized medicine.

In addition, patient education materials (literature, videotapes) and community education through the media were viewed as helpful to physicians in promoting behavior changes to reduce cancer risk. Current activities of agencies in this area should be continued.

Reducing the risk of cancer through various changes in habits can result in enormous health and economic benefits, as pointed out by many of the articles in this issue. The particular "life-style" factors that affect cancer risk are being rapidly identified with better precision and clearer specificity. Physicians recognize their role in cancer prevention and are in the ideal position to significantly affect their patients' behavior. Physicians do face obstacles that sometimes limit their abilities to address the topic of cancer prevention. However, their influence on patients, their interest in the topic, and the support provided by various agencies and organizations, can dramatically reduce cancer incidence.

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Cancer Statistics in Maryland and the United States

JOHN L. YOUNG, Jr., DrPH and JOHN W. HORM MS

Young is Chief of the Demographic Analysis Section, Biometry Branch, Division of Cancer Prevention and Control, National Cancer Institute, Bethesda, MD.

Horm is a statistician in the Demographic Analysis Section, Biometry Branch, Division of Cancer Prevention and Control, National Cancer Institute, Bethesda, MD.

Cancer is a major public health problem in the State of Maryland. Based on data from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) Program,[1] the American Cancer Society estimated that during 1984 there would be 17,000 newly diagnosed cases of cancer among Maryland residents.[2] This figure did not include cases of *in situ* carcinoma or nonmelanoma skin cancers. It was further estimated that during 1984, about 8,800 Marylanders would die from cancer. Table 1 shows the American Cancer Society's estimates of the distribution of new cancers and cancer deaths during 1984 by primary site.

In order to better understand the patterns of cancer risk throughout Maryland, a statewide incidence reporting system is being implemented. Until such time as cancer incidence data are available, some insight into the cancer burden in Maryland can be gained by examining mortality data routinely available from death certificates forwarded to the National Center for Health Statistics through the Maryland Department of Health and Mental Hygiene.

Cancer mortality data for 1976–80 have been analyzed. On the next page Table 2 shows for whites and Table 3 for nonwhites average annual age-adjusted cancer mortality rates for the total United States, the State of Maryland, each of the 23 Maryland counties, and the City of Baltimore. These rates were adjusted by the direct method using the 1980 U.S. population as weights for each five-year, age-specific mortality rate.

County data for nonwhites should be interpreted with caution since only three counties (Baltimore, Montgomery, and Prince George's) and the City of Baltimore had nonwhite populations exceeding 50,000 in the 1980 Census.[3] Since race-specific data were not available at the county level, data were not analyzed for the various nonwhite groups separately. However, 91 percent of the nonwhite population of Maryland is black. Thus, in most instances, rates for blacks are very close to those for nonwhites. The exceptions would be Montgomery County, where blacks comprise only 61 percent of the nonwhite population, and Baltimore County, where blacks comprise only 83 percent of the nonwhite population. For Baltimore City, however, blacks account for 98 percent of the nonwhites.

All Cancer Sites

For both whites and nonwhites, mortality rates for the State of Maryland were significantly higher than those for the total U.S. for all cancer sites combined. For all cancer sites combined, mortality rates were higher among nonwhites than among whites for the total state, Baltimore City, and every Maryland county except Carroll and Queen Anne's counties. There were no cancer deaths reported among nonwhites in Garrett County during the five-year period 1976 to 80. It is interesting to note that in Prince George's County, the overall cancer morality rate was essentially equal in the two groups, 200.1 per 100,000 among whites vs. 204.5 among nonwhites.

Seven Maryland counties plus the City of Baltimore had overall cancer mortality rates for whites that were significantly higher than the U.S. average as shown in Figure 1, page 74, One is struck by the fact that six of these eight areas border the western shore of the Chesapeake Bay. Further, six Maryland counties and the City of Baltimore also had mortality rates for nonwhites that were significantly higher (Figure 2, page 74). However, these counties tended to cluster on the Eastern Shore of Maryland. No Maryland county had an overall cancer mortality rate for either whites or nonwhites significantly lower than the U.S. average.

Colorectal Cancer

Cancers of the colon and rectum account for 14.6 percent of all newly diagnosed cancers and 13.6 percent of cancer deaths.[4] The State of Maryland had colorectal cancer mortality rates for both whites and nonwhites that were significantly higher than the U.S. average. Four Maryland counties and the City of Baltimore had white colorectal mortality rates significantly higher than the U.S. average (Figure 3, page 74). These counties tended to cluster along the northern border of the

Table 1. Estimated Number of New Cancer Cases and Cancer Deaths, Maryland 1984

Primary Site	Cases	Deaths
All sites	17,000	8,800
Oral cavity	400	225
Colon and rectum	2,500	1,200
Pancreas	400	400
Lung	2,700	2,500
Female breast	2,500	700
Uterus	1,100	175
Prostate	1,500	450
Leukemia	400	275

SOURCE: American Cancer Society. *Cancer Facts and Figures, 1984*

Table 2. Average Annual Age-Adjusted (1980 U.S. Standard) Cancer Mortality Rates per 100,000 Population by County for Whites of Both Sexes, Maryland 1976–80

County	All Sites	Colon and Rectum	Lung	Female Breast	Prostate
Total United States	177.5	24.3	42.6	28.2	24.2
Total State	196.8+	28.4+	49.0+	31.2+	27.6+
Allegany	195.4+	29.8+	49.2+	32.9	29.5
Anne Arundel	218.6+	29.8+	59.1+	31.2	31.4+
Baltimore	198.4+	30.0+	50.5+	32.1+	25.7
Calvert	214.4+	35.5	64.5+	28.7	20.9
Caroline	196.6	29.9	46.6	27.4	21.1
Carroll	173.5	32.3	37.0	28.2	23.4
Cecil	174.9	27.2	46.1	24.8	15.9
Charles	199.1	24.0	56.0+	38.9	24.4
Dorchester	195.3	30.3	49.9	30.6	20.4
Frederick	178.0	28.5	54.5+	22.6	26.4
Garrett	173.1	21.1	32.3−	21.2	40.2
Harford	191.9+	25.5	48.4	27.2	35.7+
Howard	175.6	28.5	38.3	28.2	26.0
Kent	162.7	13.8−	43.9	20.8	33.6
Montgomery	177.3	25.1	35.3−	36.1+	26.8
Prince George's	200.1+	25.3	49.1+	32.0+	28.7
Queen Anne's	197.1	21.2	58.4+	40.2	22.2
St. Mary's	184.4	29.7	54.5	23.8	38.2
Somerset	206.7	25.2	55.0	38.5	33.3
Talbot	185.0	24.5	40.5	39.3	32.3
Washington	183.5	32.6+	46.5	27.0	17.3−
Wicomico	197.5	26.3	57.5+	28.0	29.0
Worcester	176.4	26.8	53.0	18.7	30.8
Baltimore City	221.6+	30.6+	57.9+	29.5	30.4+

+ Rate significantly higher than the U.S. rate.
− Rate significantly lower than the U.S. rate.

Table 3. Average Annual Age-Adjusted (1980 U.S. Standard) Cancer Mortality Rates per 100,000 Population by County for Nonwhites of Both Sexes, Maryland 1976–80

County	All Sites	Colon and Rectum	Lung	Female Breast	Prostate
Total United States	206.3	23.1	47.2	25.2	43.2
Total State	247.8+	27.8+	60.6+	30.8+	53.1+
Allegany	265.8	86.4	51.0	66.5	—
Anne Arundel	232.4	28.2	53.7	31.8	46.9
Baltimore	212.5	24.4	54.1	22.7	55.3
Calvert	225.0	25.7	54.8	20.6	20.7
Caroline	286.4+	46.6	60.2	23.5	88.2
Carroll	170.3	7.4−	28.4	14.7	49.8
Cecil	214.2	34.3	59.2	49.6	45.2
Charles	216.5	25.2	52.6	42.1	44.9
Dorchester	285.2+	33.0	60.7	38.6	77.0
Frederick	314.0+	27.0	126.5+	27.6	52.4
Garrett	—	—	—	—	—
Harford	261.5	37.4	72.1	33.8	46.6
Howard	209.5	31.7	45.0	31.2	54.4
Kent	256.0	18.3	63.6	40.9	33.7
Montgomery	201.4	23.1	43.0	16.8	33.3
Prince George's	204.5	24.6	46.7	30.4	45.6
Queen Anne's	179.1	15.2	47.5	40.0	28.6
St. Mary's	260.6	25.4	55.9	29.4	64.2
Somerset	271.3+	24.9	66.8	39.6	79.5
Talbot	247.3	38.6	50.0	25.7	39.8
Washington	234.1	15.3	36.2	34.5	44.0
Wicomico	257.4+	17.2	64.2	29.0	69.8
Worcester	274.5+	25.1	82.9+	30.9	51.5
Baltimore City	268.4+	29.3+	66.6+	33.3+	56.9+

+ Rate significantly higher than the U.S. average.
− Rate significantly lower than the U.S. average.

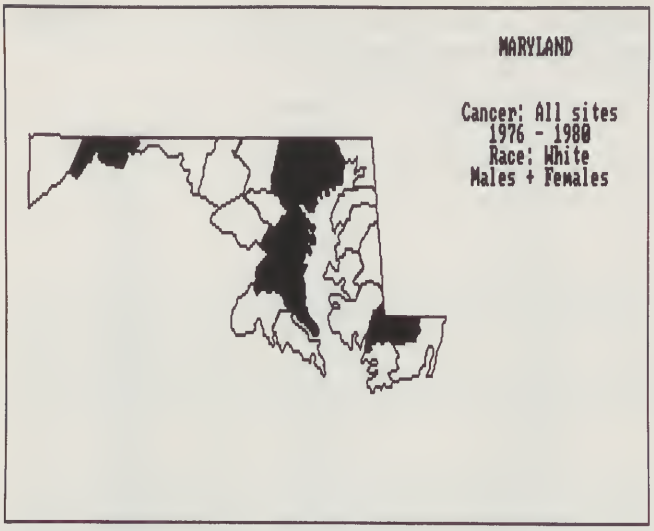


Figure 1. Maryland counties with significantly high cancer mortality, all sites combined, whites, both sexes, 1976–80

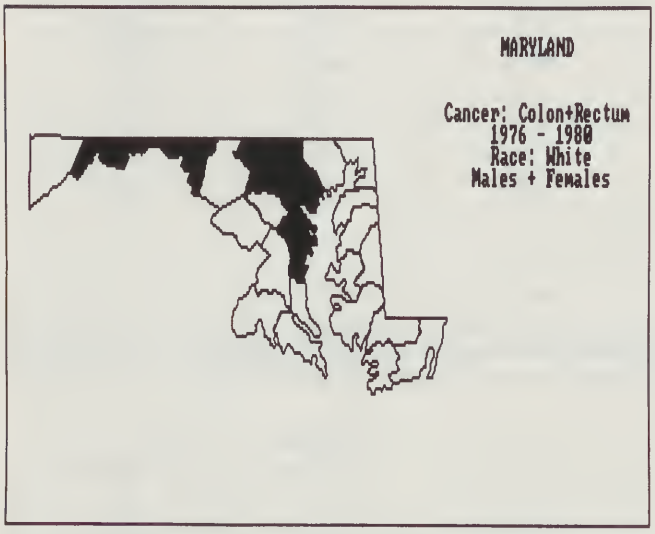


Figure 2. Maryland counties with significantly high cancer mortality, all sites combined, nonwhites, both sexes, 1976–80

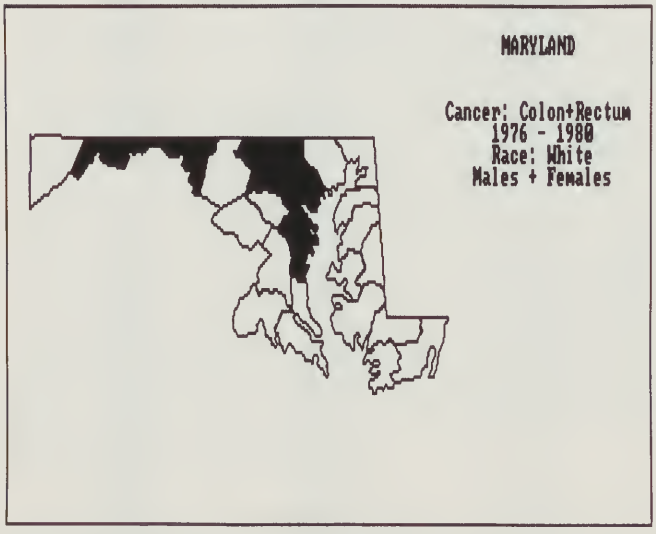


Figure 3. Maryland counties with significantly high colorectal cancer mortality, whites, both sexes, 1976–80

state. One county, Kent, had a rate among whites that was significantly lower than the corresponding U.S. rate. Among nonwhites, only the City of Baltimore had a colorectal mortality rate significantly higher than that of the U.S., while only Carroll County had a rate significantly lower. In general, mortality rates for whites and nonwhites were very similar, especially for the three most populous counties and the City of Baltimore.

Lung Cancer

Lung cancers account for approximately 15 percent of all cancer cases and 23 percent of cancer deaths. In fact, it has been projected that during 1985 lung cancer will surpass breast cancer as the leading cause of cancer death among women even though breast cancer accounts for almost 30 percent of cancer cases among women. Both whites and nonwhites had lung cancer mortality rates significantly higher than those for the U.S. when considering the state as a whole. Among whites, nine Maryland counties and the City of Baltimore had rates that were significantly higher than the U.S. rate (Figure 4, next page). There was a noticeable clustering of these counties along the western shore of the Chesapeake Bay. When white males and females were considered separately, similar patterns were noted except there were fewer counties in which females had significantly higher rates. Of particular interest, however, is the significantly low lung cancer mortality rate among whites in Montgomery County. This low rate is undoubtedly a reflection of many factors but is probably influenced by the presence of a large Hispanic population (4 percent of the total) among whom lung cancer mortality rates previously have been reported to be low.[5]

Among nonwhites, two counties and the City of Baltimore had significantly higher lung cancer mortality rates (Figure 5, next page). Similar patterns were noted among males and females. In Montgomery County, the rate for nonwhites was considerably lower than the state rate, 43.0 vs. 60.6, but the rate was not significantly lower than the U.S. rate of 47.2. In general, rates among nonwhites were higher than those among whites, as has been previously reported for blacks vs. whites.[6] However, this was not true for Prince George's County, whose nonwhite population at the time of the 1980 census was 91 percent black, and in which the white and nonwhite rates were 49.1 and 46.7 respectively.

Female Breast

Among females, breast cancer is the most common cancer accounting for 28 percent of all cases and 20 percent of all deaths due to cancer. In Maryland, both

whites and nonwhites had breast cancer mortality rates significantly higher than the United States average. Also, rates for whites and nonwhites were very similar, 31.2 vs. 30.8, respectively. Only three counties had rates for whites that were significantly higher than the U.S. average (Figure 6). It is interesting to note that these three counties—Montgomery, Prince George's, and Baltimore—are the so-called bedroom counties for Washington, DC and Baltimore City, and are, therefore, more affluent communities. Further, breast cancer incidence has been associated with high income. Among nonwhites, only the City of Baltimore had a breast cancer mortality rate significantly higher than the U.S. average. Montgomery and Baltimore counties both had nonwhite rates lower than the U.S. average.

Prostate

The State of Maryland had mortality rates from prostate cancer that were significantly higher than the U.S. average for both white and nonwhite males. Rates among nonwhites were almost double those for whites for the state as a whole, 53.1 among nonwhite males versus 27.6 among white males. Anne Arundel and Harford counties and the City of Baltimore each had rates among white males that were significantly higher than the U.S. average (Figure 7, next page), while the rate for Washington County white males was significantly lower than the U.S. average. Among nonwhites, only the City of Baltimore had a rate significantly higher than the U.S. average. It is interesting to note that the rate among nonwhites for Prince George's County, 45.6, was close to the U.S. average, while that for Montgomery County was far lower, 33.3 vs. the U.S. rate of 43.2, although not significantly lower. The lower rate in Montgomery County is probably reflective of a high proportion of Oriental males represented in the nonwhite population of that county.

Discussion

Cancer mortality in Maryland when examined by county, exhibits some interesting patterns. Among whites, the clustering of high-risk counties along the western shore of the Chesapeake Bay is similar for all cancer sites combined and for lung cancer. This configuration of counties needs further investigation to determine the contribution of smoking and occupation to these patterns. The unusual patterns for lung and prostate cancer mortality seen in Montgomery County are undoubtedly related to social phenomena such as levels of education and income, as well as smoking patterns and occupation. The rates experienced by the City of

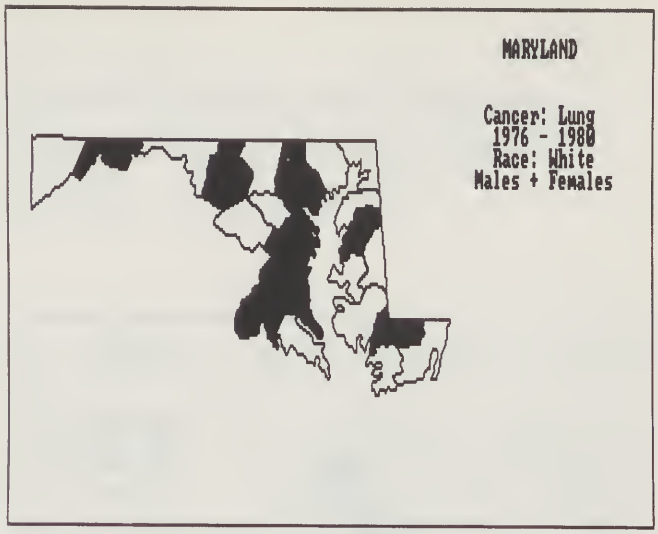


Figure 4. Maryland counties with significantly high lung cancer mortality, whites, both sexes, 1976–80

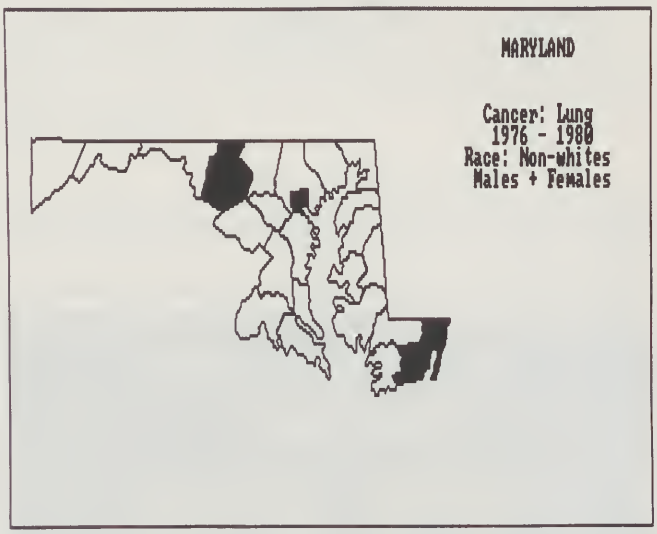


Figure 5. Maryland counties with significantly high lung cancer mortality, nonwhites, both sexes, 1976–80

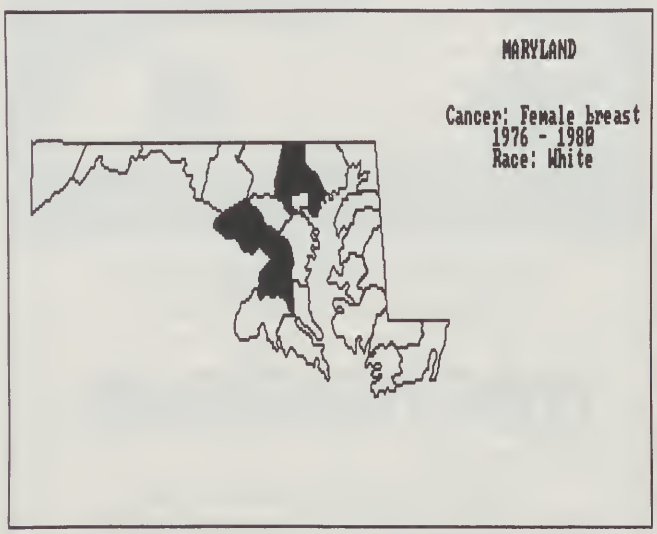


Figure 6. Maryland counties with significantly high breast cancer mortality, white females, 1976–80

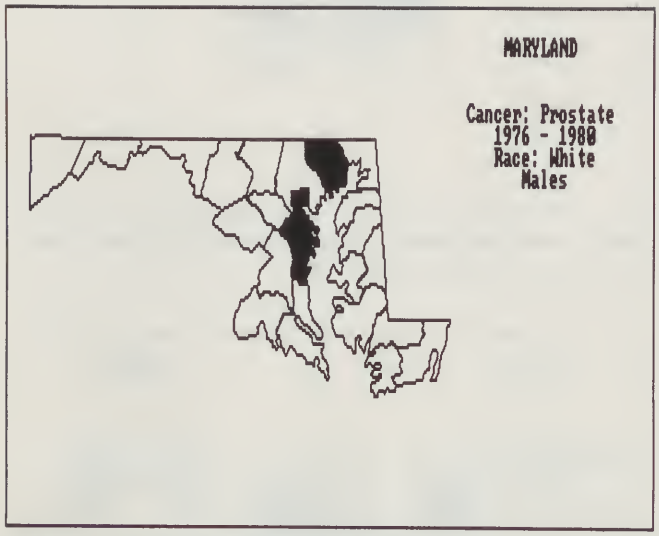


Figure 7. Maryland counties with significantly high prostate cancer mortality, white males, 1976–80

Baltimore are typical of large urban areas. Patterns for nonwhites must be interpreted with caution both because of the small nonwhite populations in the majority of Maryland counties and the heterogeneity of the nonwhite group. Ideally, rates for blacks and the various other nonwhite ethnic groups should be examined separately. Further, mortality rates for other anatomic sites such as pancreas, bladder, lymphomas, and melanomas of the skin should be examined. Finally, to fully understand cancer risk among Marylanders, cancer incidence data should be examined since cancers of many anatomic sites such as thyroid and corpus uteri have excellent survival potential and, therefore, show up infrequently in cancer mortality data. Thus, the development of cancer incidence reporting in the state should be supported on a continuing basis.

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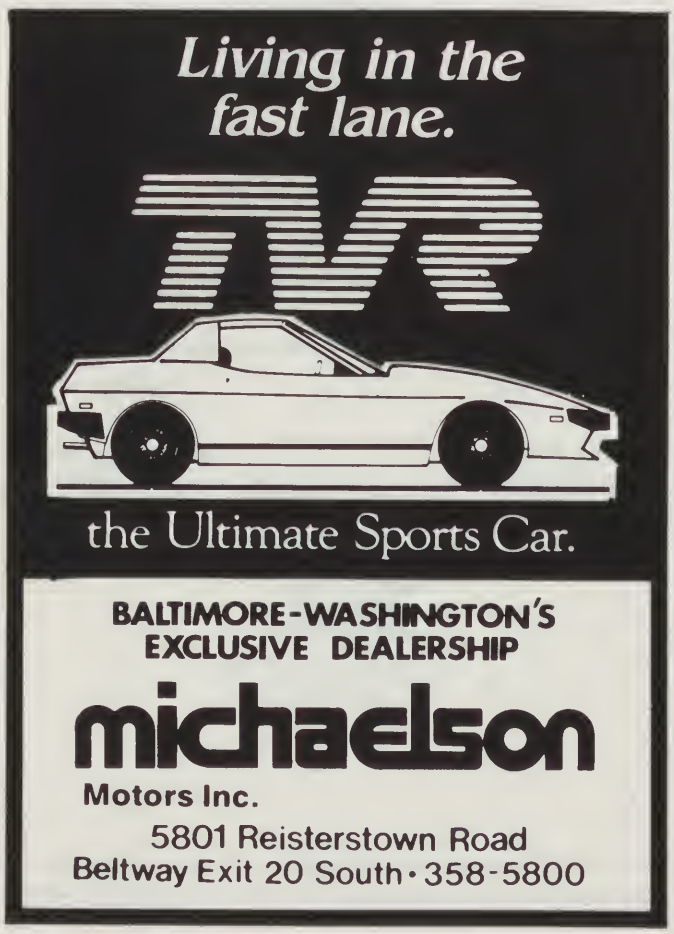
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Economic Evaluation of the Benefits of Cancer Prevention and Health Promotion Programs

ANDREW M. TAGER AB and EDWARD J. SONDIK PhD

Tager is a Kaiser Scholar in Health Policy and Management in the Whitaker College of Health Sciences, Technology and Management at the Massachusetts Institute of Technology.

Sondik is Chief, Operations Research Branch, Division of Cancer Prevention and Control, National Cancer Institute, Bethesda, MD.

In 1964, an expert committee of the World Health Organization concluded that the majority of human cancer is potentially preventable.[1] In a 1981 publication, "The Causes of Cancer: Quantitative Estimates of Avoidable Risks of Cancer in the U.S. Today," Richard Doll and Richard Peto estimated that 75 to 80 percent of incident cancer cases, in most parts of the United States, might be avoidable.[2] The reduction in cancer that health-promotion/disease-prevention programs can be expected to achieve justifies spending social resources on such programs. Beside their value in preventing human suffering, resources spent on disease prevention programs can be considered an investment.[3] Reductions in cancers that such programs achieve will decrease the aggregate social and economic costs of those illnesses. These reductions in the costs of illness can be considered benefits of the programs or returns on the investment in them. If the expected benefits of the disease-prevention programs exceed their expected costs, the programs can be considered to pay for themselves. Ultimately they are "resource sparing" rather than "resource consuming."

Cost Analysis

The comparison of a program's anticipated costs and benefits (in monetary terms) is the essence of cost-benefit analysis. This is extremely difficult to do for the benefits of health-related programs. While some health-related benefits, such as a reduction in the number of days lost from work, can be monetarily quantified, others, such as a reduction in pain suffered, cannot be. In contrast to cost-benefit analyses, cost-effectiveness analyses avoid some of these difficulties by comparing the costs of health-related programs to their nonmonetary benefits, for example, years of life gained. Alternatively, a partial estimate of the monetary value of a health program's benefits can be made by estimating the value of only those benefits that can be reasonably quantified. If the estimated value of the quantifiable benefits exceeds the estimated value of all the program's costs, then the program can be predicted to pay for itself.

In this article, we consider reductions in the costs of illness as benefits of health-promotion/disease-prevention programs and estimate the value of these benefits that can be quantified reasonably for programs aimed at two risk factors: cigarette smoking as a risk factor for lung cancer and diet as a risk factor for colorectal cancer. To do so, we use two estimates: (1) those components of the costs of lung and colorectal cancer that can be quantified reasonably and (2) estimates of the reductions in the rates of these cancers achievable by health-promotion/disease-prevention programs. The partial economic value of the programs' benefits can be thought of as the product of these two estimates. In this limited discussion, we cannot explore the range of potential health programs that might be designed to achieve these reductions in lung and colorectal cancer rates and, therefore, will not attempt here to estimate program costs or to compare our estimated values for program benefits against such costs. However, our valuation of the benefits provides a benchmark against which program designers can judge the cost savings of their programs.

Costs of Illness

We will estimate those components of the costs of lung and colorectal cancer that can be quantified in a reasonable manner. Economists and other analysts have employed roughly similar procedures for estimating components of the costs of illness. The conventional approach for estimating these components was codified by Dorothy Rice in 1966.[4] The methodology currently recommended by the U.S. Public Health Service was summarized by Thomas Hodgson and Mark Meiners.[5] The approach classifies the costs of illness into (1) direct costs, (2) indirect costs resulting from losses in economic productivity, and (3) psychosocial costs. For these categories, we discuss estimates for the costs of lung and colorectal cancers in the United States in 1980.

*1. **Direct costs*** of illness consist of medical care expenditures for diagnosis, treatment, rehabilitation, and other services, as well as nonmedical care expenditures necessitated by illness, such as transportation costs incurred by patients traveling to health-care providers.[6] Estimates of nonmedical care expenditures necessitated by illness have been made,[7] but attributing percentages of these expenditures to specific diagnoses is difficult. The magnitude of medical expenditures attributable to specific diagnoses, however, can be estimated from data collected by the Health Care Financing Administration. Hodgson calculated that the 1980 U.S. medical expenditures attributable to malignant neoplasms of the trachea, bronchus, and lung were $1,865 million and those attributable to malignant neoplasms of the digestive organs and peritoneum were $2,275 million.[8] Using the SEER program data for 1980, lung and bronchus cancers represented 98.2 percent of incident cases of cancers in the respiratory system at sites other than the larynx, nasal cavities, accessory

sinuses, and middle and inner ears. Colorectal cancers represented 63.3 percent of incident cases of digestive and peritoneal cancers.[9] Assuming analogous percentages for expenditures as for incident cases, the amount of 1980 medical expenditures attributable to lung and bronchus cancer was $1.8 billion and the amount attributable to colorectal cancer was $1.4 billion.

2. Indirect costs of illness resulting from losses in output represent the loss to the national economy from reductions in productivity due to morbidity and/or mortality.[10] The usual method for calculating these costs is the "human-capital" approach, which considers each individual as a producer of a stream of future outputs and the indirect costs of illness to be the extent to which illness interrupts that stream. The indirect costs attributable to an individual's mortality are calculated as the sum of the average yearly earnings of a person in that individual's age and sex group over the average years of life remaining for that group. Often included in the calculation of the average yearly earnings of given age and sex groups is the market value for housekeeping services performed by members of that group, computed as the cost of having those services performed by labor from the marketplace.

In calculating these costs of illness, future earnings must be discounted to their present value, as receiving a certain amount of money at some point in the future is less valuable than receiving the same amount now. The question of what value to use for the discount rate in these calculations is highly significant, because the value used has a large effect on the present value of future earnings. Analysts generally agree that the appropriate discount rate to use for these calculations is the so-called social rate of time preference, which represents the extent of society's preference for near-term vs. distant future benefits. However, this rate is not observable, and its actual value is uncertain. Hodgson and Meiners recommend that the indirect cost of mortality be calculated at least twice using alternative discount rates.[11] They report that rates generally used in cost-of-illness calculations range from 2.5 percent to 10 percent, and the social rate of time preference is thought to be between 2.5 percent and 6 percent.

Rice, Hodgson, and Kopstein have calculated the 1980 value of lifetime earnings of age and sex discounted at 4 and 6 percent.[12] In this article we use the values they calculated based on a 4 percent discount rate. Taking these values and the 1980 United States age and sex specific mortality frequencies for lung and bronchus cancer and colorectal cancer, the 1980 indirect costs of mortality were $7.8 billion for lung and bronchus cancer and $3.6 billion for colorectal cancer, as calculated in Tables 1 and 2, next page. In contrast, using a 6 percent discount rate, Hodgson and Rice calculated that the 1977 indirect costs of mortality due to cancers of respiratory organs were $5 billion, and those due to cancers of digestive organs were $3.8 billion.[13]

As earnings do not capture the value of human life, these human capital calculations do not quantify the value of years of life lost. Using human-capital calculations to do so would place greater value on years lost by persons or groups of persons with greater earnings. Instead, we use human-capital calculations to quantify only one specific component of the value of the years of life lost, the value of persons' productive labor to the national economy as measured by their earnings.

Analysts have raised concern about using this approach to value persons' productive labor. The human-capital methodology is based on the assumption that a person's earnings reflects his/her productivity, an assumption that does not hold in the presence of discrimination by age, sex, race, or ethnicity that generates unequal pay for equal work, or other imperfections in the labor market.[14] In the presence of discrimination, this method will undervalue years prematurely lost by groups that experience discrimination relative to groups that do not. Another concern is that the adjustment of a group's average yearly earning mentioned for household services may be incomplete and hence, misleading.[15]

The costs of advertising for, hiring, and training a new employee to replace someone dying from cancer have been considered as indirect costs of mortality in some calculations. Eddy estimated this cost to be $3,500 per replacement in 1980 for workers between the ages of 20 and 65 in private industry. Using this estimate, Eddy calculated that the 1980 workers' replacement costs in private industry due to lung cancer were $57 million and those due to colorectal cancer were $22.7 million.[16] The workers considered represent approximately two-thirds of persons employed in the United States; hence, equivalent estimates for the entire employed population would be greater.

Calculations of the indirect costs attributable to morbidity have included cost of sick-leave pay and cost of lower productivity of temporary substitutes relative to the workers they replace. Assuming sick-leave pay to be 60 percent of regular salary and temporary substitutes to be paid at the same rates as the workers they replace (but only 75 percent as productive), Eddy calculated these costs to be $61.9 million for lung cancer and $37 million for colon cancer in 1980[17] for workers between the ages of 20 and 65 in private industry.

3. Psychosocial costs represent the wide variety of deteriorations in the quality of life of those affected by the physical and emotional traumas of cancer. Approaches for considering these costs are widely debated,

Table 1. Frequencies and Indirect Costs of Mortalities due to Lung Cancer in 1980 by Age and Sex (in millions of dollars)

Age	Men		Women	
	Mortalities	Indirect cost of mortality	Mortalities	Indirect cost of mortality
0–4	5	$ 2.1	3	$ 1.0
5–9	1	0.5	3	1.1
10–14	3	1.6	0	0.0
15–19	2	1.2	2	0.9
20–24	15	9.1	2	0.9
25–29	36	21.5	19	8.0
30–34	108	60.2	69	25.7
35–39	396	194.9	233	75.1
40–44	1097	452.8	620	167.7
45–49	2662	867.7	1348	292.2
50–54	5687	1339.1	2618	426.8
55–59	9346	1356.2	3751	418.8
60–64	12,309	830.2	4541	305.5
65–69	14,211	367.9	4913	182.3
70–74	13,048	165.3	4131	84.9
75–79	9167	56.0	2903	31.8
80–84	4822	14.5	1667	7.2
85+	2509	2.3	1429	1.7
Total	75,424	$5743.1	28,252	$2031.6

SOURCE: Mortality data—National Center for Health Statistics (NCHS). Public-user tape obtained by the SEER Program.

Table 2. Frequencies and Indirect Costs of Mortalities due to Colorectal Cancer in 1980 by Age and Sex (in millions of dollars)

Age	Men		Women	
	Mortalities	Indirect cost of mortality	Mortalities	Indirect cost of mortality
0–4	1	$ 0.4	1	$ 0.3
5–9	0	0.0	1	0.4
10–14	0	0.0	3	1.3
15–19	9	5.2	10	4.5
20–24	24	14.5	39	17.5
25–29	47	28.1	91	38.1
30–34	102	56.8	154	57.4
35–39	168	82.7	308	99.3
40–44	295	121.8	514	139.0
45–49	533	173.7	978	212.0
50–54	1134	267.0	2008	327.3
55–59	1954	283.5	3731	416.5
60–64	2653	178.9	5143	346.0
65–69	3583	92.8	7130	264.6
70–74	4355	55.2	8051	165.5
75–79	4455	27.2	7956	87.1
80–84	4176	12.5	6685	29.0
85+	4527	4.1	6729	8.1
Total	28,016	$1404.4	49,532	$2213.9

SOURCE: Mortality data—National Center for Health Statistics (NCHS). Public-user tape obtained by the SEER Program.

and quantifying them remains rather intractable.[18] Therefore, we will not attempt to include these in our estimates.

Summations of estimates of certain components of the costs of lung and colorectal cancers can be thought of as partial estimates of (or lower bounds for) their total costs. In no way do we mean to imply that the costs we considered are more significant than those we did not consider, but only that the estimate of certain components of the costs of illness may provide information that if considered appropriately, may be useful in performing cost-benefit analyses.

As estimated for lung cancer, the direct costs of medical expenditures in 1980 were $1.8 billion; the indirect costs of sick-leave pay, diminished productivity, and worker replacement were $118.9 million; the indirect costs of lost earnings were $7.8 billion. Adding these three components to arrive at a partial estimate, the economic costs of lung cancer in the United States in 1980 were at least $9.7 billion. Similarly, for colorectal cancer in 1980, the direct costs of medical expenditures were $1.4 billion; the indirect costs of sick leave pay, diminished productivity, and worker replacement were $59.7 million; and the indirect costs of lost earnings were $3.6 billion. Adding these three components, the economic costs of colorectal cancer in the United States in 1980 were at least $5.1 billion.

Reduction in Lung Cancer

As concluded in the 1982 Surgeon General's Report, *The Health Consequences of Smoking: Cancer*, cigarette smoking is the major cause of lung cancer in the United States.[19] To estimate the proportion of U.S. lung cancer deaths in 1978 attributable to tobacco, Doll and Peto compared the actual number of lung cancer deaths occurring that year to the number that would have been predicted to occur if age and sex specific lung cancer mortality rates observed for persons who never smoked regularly applied to the whole country. The age and sex specific lung cancer mortality rates used for persons never smoking regularly were those observed during 1959 to 72 for 500,000 Americans who in 1959 said they had never smoked regularly and whose subsequent mortality was monitored by the American Cancer Society. Using this approach, Doll and Peto estimated that 80,000 to 85,000 of the 95,000 deaths from lung cancer in the U.S. in 1978 (approximately 85 to 90 percent) were attributable to tobacco.[20]

We will calculate partial estimates of the benefits that would result from smoking-cessation-and-prevention programs if they achieved 10 percent to 100 percent reductions in U.S. smoking rates. To rigorously predict the reduction in lung cancer that will result from the range of possible reductions in cigarette smoking, one must consider how former smokers' risks for cancer change in time after quitting, depending on such factors as the number of cigarettes they smoked per day and the number of years they smoked. (This analysis is being performed currently at the National Cancer Institute.) In this article, we estimate the order of magnitude of the potential cost savings of smoking cessation programs by assuming that the complete elimination of smoking in the U.S. would eventually reduce lung cancer by 90 percent, and that intermediate reductions in smoking would eventually reduce lung cancer by proportional amounts. For example, making the assumption that eventually 50 percent of smoking in the U.S. might be eliminated would lead to a lung cancer reduction of 45 percent. Similarly, elimination of 10 percent, 25 percent, or 75 percent of smoking in the U.S. would be expected eventually to reduce lung cancer by 9 percent, 22.5 percent, or 67.5 percent respectively. We will calculate partial estimates of the benefits that would result from smoking cessation programs if they eventually achieved 9 percent, 22.5 percent, 45 percent, 67.5 percent, or 90 percent reductions in U.S lung cancer rates.

Reduction in Colorectal Cancer

Although there has been strong but indirect evidence for many years that the nation's cancer burden could be reduced by suitable modification of its dietary practices, the relationship between diet and cancer is known less precisely than that between smoking and cancer. After an extensive review of available information, Doll and Peto estimated it may be possible by practicable dietary means to reduce the U.S. death rate due to cancers of all sites by 10 to 70 percent, their best estimate being 35 percent. They estimated it may be possible to reduce the death rate due to cancer of the large bowel by as much as 90 percent.[21] The National Cancer Institute has estimated that a 25 percent reduction in fat content of the U.S. diet could reduce colorectal cancer mortality by 25 percent.[22] We will calculate partial estimates of the benefits that would result from dietary education programs if they achieved 10 percent, 25 percent, 35 percent, 70 percent, or 90 percent reductions in U.S. colorectal cancer rates.

Costs Saved by Prevention Programs

As indicated, we will consider the economic benefits of disease prevention programs to be the costs of illness avoided by the reductions in cancer they achieve. We can arrive at partial estimates of the value of these benefits by multiplying the partial estimates of the yearly costs of lung and colorectal cancer by estimates

of the reductions in these cancers achievable by disease-prevention/health-promotion programs. Smoking-cessation-and-prevention programs achieving 9 percent, 22.5 percent, 45 percent, 67.5 percent, or 90 percent reductions in U.S. lung cancer rates would reduce the costs of lung cancer in the U.S. by at least $0.9 billion, $2.2 billion, $4.4 billion, $6.5 billion, or $8.7 billion per year, respectively. The lowest of this series ($0.9 billion) represents approximately half the cost of medical services consumed by lung cancer in 1980. Dietary education programs achieving 10 percent, 25 percent, 35 percent, 70 percent, or 90 percent reductions in U.S. colorectal cancer rates would reduce the yearly costs of colorectal cancer in the U.S. by at least $0.5 billion, $1.3 billion, $1.8 billion, $3.6 billion or $4.6 billion per year, respectively. The lowest of this series ($0.5 billion) is more than one-third of the cost of colorectal medical services in 1980.

There are several conceptual issues that bear discussion regarding the approach we used to estimate costs saved by prevention programs. Our estimates for the costs of lung and colorectal cancer are based on the number of prevalent cases of those illnesses in 1980. Cases diagnosed prior to that year, as well as cases diagnosed during that year, contribute to this number of cases and hence, to the total cost. Disease prevention programs, on the other hand, will reduce the future number of incident cases but will not affect the number of prevalent cases that began prior to the programs' inceptions. The costs saved by prevention programs will then be the costs of future incident cases they prevent.

Determining the costs of future incident cases is complicated by the need to determine the parameters of the clinical course of the "average" incident case, such as the average number of hospital days per case from onset to cure or death. Some authors have demonstrated methods for approaching these problems.[23] In the long run, however, consistent changes in incidence rates should result in proportional changes in prevalence rates. Therefore, the magnitude of the long-term cost savings of prevention programs can be estimated using the approach we have taken.

A second issue is how to consider the broader impact of prevention programs on the future direct costs of illness. Consider for example, a person who would have had a fatal case of cancer who remains cancer free because of health promotional efforts. The cost of the medical services that would have been used during the fatal case will be saved. However, in the absence of the fatal case, the person is likely to require some amount of medical services for other illnesses experienced during the rest of his/her lifetime.[24] The net savings of prevention programs in terms of direct costs, therefore, become the cost of services that would have been required in the cases prevented by the program minus the discounted value of future medical services used by persons whose deaths the programs prevent.

A third issue is how to consider the broader impact on the economy of the changes in the demographic profile of the population that may result from disease prevention programs. Gori and Richter have raised the possibility that demographic changes produced by prevention programs, augmenting the aging of the U.S. population, may increase the socioeconomic complications some analysts forecast will accompany that aging.[25] The cost of such complications can be considered when estimating program costs in a complete cost-benefit analysis.

Conclusion

We have attempted to value in economic terms the benefits of cigarette smoking cessation and dietary education programs. As indicated, numerous assumptions were made in calculating these estimates. Given these assumptions, the values calculated represent partial estimates, or estimates of the lower bounds of the benefits of these programs, rather than estimates of the benefits themselves, due to the costs as well as the illnesses not considered. First, as already discussed, the estimates do not consider the psychosocial and certain other costs of lung and colorectal cancer. Second, the estimates do not consider the reduction in other cancers and other nonneoplastic diseases that smoking cessation and dietary education programs can achieve. In estimating 35 percent of all U.S. cancers to be potentially avoidable by practicable dietary means, Doll and Peto considered potential reductions in cancers of the stomach, endometrium, gallbladder, pancreas, breast, lung, larynx, bladder, cervix, mouth, pharynx, and esophagus, as well as cancers of the large bowel.[26]

In addition to being the major cause of lung cancer, the 1982 Surgeon General's report concludes cigarette smoking is the major cause of laryngeal cancer; a major cause of oral and esophageal cancer; a contributing factor in the development of bladder, kidney, and pancreatic cancer; and may be involved in cancer of the uterine cervix.[27] Further, in estimating the total economic cost of illness due to smoking, Rice and Hodgson considered the contributions of smoking to the following nonneoplastic diseases: tuberculosis, hypertension, ischemic heart disease, cerebrovascular lesions, arteriosclerosis, aortic aneurysms, influenza, pneumonia, chronic bronchitis, emphysema, asthma, gastric ulcers, duodenal ulcers and cirrhosis. Of their $42.2 billion estimate for the total cost of illness incurred in 1980

due to smoking, neoplastic diseases account for $11 billion or 26 percent.[28]

As we have not discussed specific prevention programs, it is not possible for us to estimate the costs of establishing and running the programs or combination of programs necessary to achieve the targeted reductions in illness. For this reason, a formal cost-benefit analysis of cancer prevention programs cannot be completed here. However, using the methods discussed, such an analysis can be performed for a specific program whose costs and expected reductions in illness can be estimated. If the estimated costs of a given program do not exceed the estimated lower bound of its benefits, then the program can be predicted to be ultimately resource sparing rather than resource consuming.

The reductions in human suffering that disease prevention programs can achieve justify spending social resources on such programs. Hence, whereas the prediction of a particular program to be resource sparing certainly supports instituting the program, the prediction of a program to be resource consuming, by any methodology, cannot by itself be taken as a reason for not instituting the program.

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Resources: Cancer Prevention

DONNA S. COX MEd and KAY C. VANSANT

Cox is Director, Cancer Communications, The Johns Hopkins Oncology Center and VanSant is Medical Affairs Director, American Cancer Society Maryland Division, Inc.

Ten years ago scientists understood very little about cancer prevention. Today we know that up to 80 percent of cancer cases may be associated with "life-style"—the foods people eat, the work they do, and whether they smoke. Individuals are becoming aware of cancer prevention, and they increasingly are questioning their physicians about it.

The Cancer Information Service (CIS), a program of the Johns Hopkins Oncology Center, and the American Cancer Society Maryland Division, Inc., prepared a directory identifying cancer prevention resources to assist physicians. It is intended to provide physicians with an awareness of continuing medical education programs, audiovisual materials, printed information, and referral resources for smoking cessation and cancer screening programs. Resources are arranged in four sections: Agencies/Organizations, Smoking, Secondary Prevention, and Publications. Significant excerpts are provided here. To obtain a complete copy of the directory, please contact the Cancer Information Service at 1-800-4-CANCER.

Agencies/Organizations

Although there are many agencies and organizations in Maryland that provide services and/or materials concerning cancer prevention, there are two organizations that have cancer education as a major component of their mandates: The Cancer Information Service and the American Cancer Society Maryland Division, Inc.

The Cancer Information Service (CIS) is a toll-free telephone inquiry program that supplies information about cancer and cancer-related resources to physicians, allied health professionals, cancer patients, their families, and the general public. It is part of a national network of cancer communication offices. In Maryland, the CIS operates under the sponsorship of the Johns Hopkins Oncology Center and is funded by the National Cancer Institute.

The public's fear of cancer and confusion about the facts were factors leading to the formation of the CIS. The service was created to provide rapid access to the latest information about cancer, to address the particular needs of the Maryland population, and to bridge the gap between cancer knowledge and personal action. An important objective of the CIS is to increase public awareness of the vital role individuals can play in both the prevention of the disease and early detection, which in many cases can lead to increased survival.

CIS does not provide diagnosis or treatment recommendations relating to the individual situations of the callers. Information provided may be specific about the subject, but each caller is advised to check with his or her own physician about its applicability to his or her particular case. There is no charge for the calls or for information provided.

The CIS serves as a central source for referral to local cancer-related service programs and as a contact point for information about the latest in cancer research. In addition to providing assistance over the telephone, the CIS office provides complimentary printed materials that target the physician, as well as language-adjusted information for the general public on a variety of subjects including cancer risks, primary and secondary prevention, types of cancer, and cancer treatment.

The CIS also maintains a listing of both nonprofit and commercial organizations throughout the State of Maryland that offer stop-smoking clinics, self-help materials, maintenance programs, and individual approaches.

The Cancer Information Service may be reached by dialing 1-800-4-CANCER, 8:30 a.m. to 5:00 p.m. weekdays, or writing **Cancer Information Service**, Johns Hopkins Oncology Center, Suite 307, 550 North Broadway, Baltimore, MD 21205.

The American Cancer Society, Inc. is a national voluntary health organization of 2.5 million Americans united to conquer cancer through balanced programs of research, education, patient service, and rehabilitation.

The Society maintains its priorities and goals through activities developed by the departments of Research, Professional Education, Public Education, Public Information, Epidemiology and Statistics, Service, and Rehabilitation and Crusade.

The American Cancer Society's Professional Education program brings the latest developments in cancer control to the medical community. National, Division and Unit meetings, conferences, seminars, workshops, and scholarships provide information and training in the prevention and early detection of cancer, and in the treatment and rehabilitation of cancer patients.

Because thousands of lives could be saved each year through cancer prevention and early detection, the Society's Public Education programs are designed to inform the public about cancer, tell them what they can do to protect themselves, and demonstrate related-health practices. The Society believes strongly in the value of periodic, cancer-related checkups and specific cancer tests, as well as prompt action in the event that one of cancer's seven warning signals occurs.

The American Cancer Society is also one of the largest sources of cancer research funds in the United States, including ongoing interferon research, investigation into chemoprevention, and studies of agents such

as vitamins A, C, and E, retinoids, and chemicals such as selenium. In addition, one of the major undertakings of the ACS is to help identify environmental factors in human cancer in the Cancer Prevention Study II. CPS-II is a long-term prospective study of the habits and exposures of more than one million Americans. It seeks to identify factors that increase a person's chances of getting cancer, those that carry little or no risk, and those that actually may help prevent cancer.

The American Cancer Society has nine offices in Maryland.

Office	Telephone
Chesapeake-Potomac	757-7447 or 757-7448
Hyattsville	864-7361 or 864-6035
Metropolitan Baltimore	828-8890
Allegany County Unit	722-2145
Northern Area	296-8254
Frederick County Unit	662-2357
Montgomery County Unit	933-9350
Eastern Shore Area	749-1624
Hagerstown	733-8272

In addition to the Cancer Information Service and the American Cancer Society Maryland Division, a number of local agencies and organizations provide either services or printed materials for the physician and/or patient. The following agency descriptions focus only on the cancer prevention services they offer:

Alcoholism Control Administration: 383-2781
Offers general information concerning alcohol consumption and provides statewide referrals to programs on alcoholism.

American Heart Association Maryland Affiliate, Inc.: 685-7074
Provides booklets on How to Stop Smoking, Weight Control Guidelines in Smoking Cessation, and Children and Smoking.

American Lung Association of Maryland: 1-800-492-7527
Conducts smoking cessation programs throughout the State; offers a variety of literature concerning tobacco usage, second-hand smoke, smoking cessation, and maintenance.

Cancer Prevention Awareness Program, National Cancer Institute: 469-6792
This program targets the general public as well as populations at greater-than-average risk for developing cancer. Offers free materials explaining risk factors and ways to reduce them.

Cancer Registry: 383-2740
The Cancer Registry was established to record newly diagnosed cancer cases. With plans to expand statewide, it is now collecting data from several Baltimore area hospitals. When fully operational, the data base can be cross-linked with the Birth Defects and Toxic Substances registries to search for suspected common causes and to help develop protective measures.

Center for Health Education, Inc.: 837-2705
CHE implements programs for physicians that will help increase patients' adherence to medical advice; develops training sessions for physicians in the techniques of promoting wellness among their patients; offers opportunities for physicians to improve their communication skills with patients; and serves as a resource for information regarding health education activities for physicians.

Division of Cancer Control: 383-2286
Assumes responsibility for advising physicians throughout the state of new information from CDC. Provides support to statewide cervical screening programs.

Food and Drug Administration: 962-3731
Stresses the safest, most effective use of foods, drugs, cosmetics, medical devices, radiological and vaccine/biological products in order to minimize exposure to carcinogens.

Food & Nutrition Information Center: 344-5719
Provides a registered dietitian on staff to answer public inquiries concerning food and nutrition.

Health Departments
Most Health Departments provide breast, cervical and/or colorectal screening for a minimal fee, and many offer smoking cessation programs.

Allegany	777-5600
Anne Arundel	224-7095
Baltimore City	396-4399
Baltimore	494-2702
Calvert	535-0128
Caroline	479-0556
Carroll	875-3390
Cecil	398-5100
Charles	934-9577
Dorchester	228-3223
Frederick	694-1700
Garrett	334-8111
Harford	838-6000
Howard	992-2333
Kent	778-1350
Montgomery	593-8505
Prince George's	386-0150
Queen Anne's	758-0720
St. Mary's	475-8921
Somerset	651-0822
Talbot	822-2292
Washington	791-3200

Wicomico	749-1244
Worchester	632-1100

Healthy People Project: 383-4077

Audio-visual materials on smoking, nutrition and "life-style" are available on loan. Also offers free literature.

Hospitals

Most hospitals provide cervical, breast and colorectal screening. Many community hospitals conduct smoking cessation programs at various times throughout the year. A complete list of Maryland hospitals may be obtained from the Cancer Information Service 1-800-4-CANCER.

Interagency Task Force on Smoking: 383-4077

An interagency group formed to address the problems of tobacco usage, it conducts an annual, statewide smoking cessation intervention activity.

Maryland Occupational Safety and Health: 659-4196

Maryland Occupational Safety and Health provides: (1) large library of occupational health references and source books; (2) series of slide/tape presentations detailing hazards of asbestos, safe work practices, and employee/employer rights under the MOSH law; (3) laboratory identification of bulk and airborne samples for asbestos content as part of consultation or enforcement cases; (4) on-site consultation with private-sector employers to determine compliance with asbestos regulations. This is a free service to Maryland employers. Results are not transmitted to enforcement personnel.

Tel-Med Program of Maryland: 539-0872

A statewide telephone library program coordinated by the Medical and Chirurgical Faculty of Maryland. Telephone libraries play taped messages on selected subjects (for instance, smoking). Programs have been established at various locations throughout the state. Call 539-0872 to find the Tel-Med site nearest you.

Smoking

Although it is true that most people are recovering from most forms of cancer, the overall mortality (total deaths from all forms) has remained about level during the past decade. This is primarily due to the sharp rise in lung cancer among women. Lung cancer is expected to surpass breast cancer this year as the leading cause of death in women.

We know that the incidence of lung cancer could be reduced by approximately 90 percent simply by avoiding tobacco. Since most of the cancer mortality in the United States can be attributed to smoking-related cancers (mouth, larynx, esophagus, bladder, kidney, and pancreas), smoking cessation would save thousands of lives.

Therefore, this section identifies various types of smoking-cessation programs. Guidelines for selecting a smoking-cessation program have been included. These guidelines are provided to assist physicians in helping patients select the particular type of program with which they would feel most comfortable. Additional information may be obtained from the Cancer Information Service (1-800-4-CANCER), which maintains a statewide calendar of scheduled smoking-cessation programs.

Guidelines for Selecting A Smoking-Cessation Program

Listed below are several questions which may be helpful to your patients in selecting a smoking cessation program.

Methods

1. What are the cessation methods used?
2. How many sessions are involved?
3. How many total hours?
4. Is the role of the participants active or passive?
5. What type of follow-up support does the program provide?
6. Are reinforcement sessions available? At what cost?
7. Who conducts the program? How are they trained?

Success Rate

1. What is the success rate?
2. How is the success rate measured?
   (a) Does it reflect participants who completely quit or just reduce smoking?
   (b) Does it reflect participants who begin the program or those who complete the program?
   (c) Is the success rate determined immediately after the program, 6 months later, or one year later?
3. How many people usually drop out during the program?

Costs

1. What does the total program cost?
2. Are additional materials recommended? What do they cost?
3. Is a deposit required?
4. Is the balance due on admission or over a period of time?
5. Are refunds offered?

Group Smoking-Cessation Programs Offered by Maryland Organizations

Agency/Organization	Program Description
American Cancer Society	Films for adults and youth, posters, worksite programs. "Fresh Start" Stop Smoking Clinics. Contact: Local ACS offices.
American Lung Association: Freedom From Smoking Clinic	Fee: $25. Programs offered at various times of the year throughout Maryland. Five to eight 2-hr sessions include self-testing, a variety of audiovisuals, group support, and discussion. Contact: ALAM at 685-6484 or 1-800-492-7527.
Local Health Departments	Many local Health Departments offer cessation programs at various times throughout the year. Contact: local health departments.
Seventh-Day Adventists	Fee: $25–$35 to cover materials. Sessions 1.5 hr long use films, discussion, group dynamics, diet information, and a control booklet. Contact: Chesapeake Conference of Seventh Day Adventists in Columbia, MD 995-1910.
SmokEnders	Fee: $295. Eight Weekly 2-hr sessions including lectures, group, and individual activities. Sessions are regularly scheduled in Maryland. Contact: 202-463-7867.

Hospital/HMO-Based Group Smoking-Cessation Programs

Location	Site	Program Description
Baltimore City	St. Agnes Hospital	Minimal refundable fee. Offers program in cooperation with the American Cancer Society 4 or 5 times/yr. Contact Hospital Education 368-6446.
Baltimore County	Baltimore County General Hospital	Fee: $25. Offers 3 or 4 programs/yr. Contact: Human Resources Development 521-5968.
Howard County	Columbia Medical Plan	Standard copayment fee for members and $8/hr for nonmembers. Offers clinic—one session/wk for 4 wks plus four follow-up sessions. Contact: 992-4242.

Kent County	Kent County Stop Smoking Program	No fee. Program uses self-testing, group support, and speakers in 5-session format. Programs held periodically throughout the year at various locations in the county and are cosponsored with other groups. Contact: KCHD 778-2616 or 778-1350.
Talbot County	Talbot County Stop Smoking Program	Fee: $10–25. Two stop-smoking clinics/yr held in various locations throughout the county are cosponsored with other groups. Clinics involve from 5 to 8 sessions. Contact: the County Health Department at 822-7844 or 822-2292.

Individual Smoking-Cessation Programs

Counseling

Columbia Medical Plan	Fee: members standard copayment; nonmembers, $28 first visit. Individual counseling. Contact: Health Education 992-4242.

Hypnosis

Academy of Applied Hypnosis	Fee: $100 for one 2.5 hr session. Contact: James R. Lewis at 821-6055.
Baltimore County Smoking Clinic	Fee: $105. Includes two 1.5 hr sessions a month apart. Contact: James White, 668-1426.
Reducing Key Hypnosis Center	Fee: $50. $25 each 1/2 hour follow-up session. Includes individual counseling and hypnotherapy in 3 or 4 sessions, following cold-turkey approach. Contact: Glen Burnie 760-3590; Pikesville 358-8616; Laurel 792-9215.
Weight Control Institute	Fee: $140. Four weekly group sessions using self-hypnosis. Contact: 282-6600.

Smoking-Cessation Programs for Youth

Youth Smoking-Cessation Clinic	American Cancer Society. Target group: 15 to 18 years. Implemented during school day for a minimum of 9 one-hr sessions. Includes self-management techniques, the development of personal responsibility in decision making, and group support activities. Contact: Public Education Director, American Cancer Society, Maryland Division, 828-8890.
Teen Quit-Smoking Clinic	American Lung Association of Maryland. Target group: 13 to 19 years. Uses selected

concepts derived from the ALA Freedom from Smoking Clinic and ACS Youth Smoking Cessation Clinic and the American Health Foundation Smoke-Stoppers Clinic plus various other materials and techniques. Contact: ALA 685-6484 or 1-800-492-7527.

Smoking-Cessation Maintenance Programs

Ex-Smokers United—North Central Lung Association	Fee: None. Informal support group meets once a month at Baltimore County General Hospital and Greater Baltimore Medical Center to help people who have become nonsmokers remain so. Discussion and some guest speakers. Contact: NCLA 252-3091.

Tel-Med; Smoking Related Taped Messages

Title	Tape No.
Cigarette Smoking and Heart Disease	21
Weight Control While Quitting	693
Why a Woman Should Quit Smoking	694
Reducing the Risks of Smoking	695
How Smoking Affects Your Health	696
Do You Want To Quit Smoking?	697
What Do You Get Out Of Smoking?	698
Gimmicks To Help You Quit Smoking	699
Effects of Cigarette Smoke on Non-Smokers	700

Call 539-0872 for the Tel-Med program nearest your.

Secondary Prevention

Due to ignorance or fear many cancer victims do not seek medical help until the cancer has metastasized. Once this happens, survival rates are much lower than for patients treated in early stages of the disease. The critical factor is early diagnosis. If the tumor is detected and attacked while still localized, there is excellent opportunity for a cure. With early detection, chances of complete recovery are up to 50 percent higher than the average five-year survival rates.

As has been noted in the section on Agencies/Organizations, county health departments and most community hospitals provide early detection services. In addition, the Cancer Information Service has information on seven Cancer Screening Centers in Maryland, including their location, fee structure, and the services provided.

Educational Materials

Both the Cancer Information Service and the American Cancer Society Maryland Division, Inc. offer a wide range of cancer prevention-related materials for both physicians and the patient/public population. Copies of the physician-oriented publications listed are available by contacting the appropriate organization. In addition, CIS and ACS can provide descriptions and/or copies of a wide variety of free patient-education materials. All materials are available from CIS (1-800-4-CANCER) unless otherwise indicated.

A. Primary Prevention Materials for Physicians

- *National Cancer Institute Guidelines on Diet, Nutrition and Cancer.* Explores the role of diet and nutrition in causation, prevention, and treatment of cancer. NCI, May 1982.
- *Cancer Prevention Awareness Program.* A compendium of information concerning the rationale, intent, methodology, implementation, and evaluation of the National Cancer Institute's Cancer Prevention Awareness Program. NCI/OCC, 1984.
- *Staying Healthy—A Bibliography of Health Promotion Materials.* Gives a brief description of materials on a wide variety of topics, for example, cancer, health promotion, nutrition, smoking, X-rays. U.S. DHHS, Public Health Service, May 1983.
- *A Time of Change: Health Information for Young Hispanic Women: A Leader's Guide for Group Discussions on Health Promotion.* Covers breast self-examination, pelvic exams, smoking, drug abuse, nutrition, exercises, and resources. NCI/OCC, August 1982.
- *Cancer Prevention Research Summary:*
  1. ALCOHOL
  2. ESTROGENS
  3. VIRUSES
  4. TOBACCO

  U.S. DHHS, NIH/NCI, February 1984.

The following materials are available from ACS:

- *Clinical Oncology for Medical Students and Physicians—A Multidisciplinary Approach.* 6th Edition (#3021)
- *Guidelines for the Cancer-Related Check-up: Recommendations and Rationale.* (#3347)
- *Cancer—A Manual for Practitioners.* 6th Edition (#3499)
- *Public Attitudes Toward Cancer and Cancer Tests.* (#3322)
- *Opinion: Is There A Cancer-Prone Personality?* (#3338)
- *Carcinogens in the Workplace.* (#3413)

B. Secondary Prevention Materials for Physicians

- *Breast Cancer Digest.* A guide to medical care, emotional support, educational programs, and resources. NCI, April 1984.
- *Cervical Cancer Screening: The Pap Smear.* Discusses the background and effect this test has had on cervical cancer rates. U.S. DHHS, Public Health Service, NIH 1980.
- *Prenatal DES Exposure: Recommendations of the Diethylstilbestrol—Adenosis Project for the Identification and Management of Exposed Individuals.* Provides current information on the health status of DES-exposed persons, methods available for their identification, and plans for continuing examination and management. NCI, March 1981.

Breast

- *Breast Self-Examination: Key Role of the Physician* (#3016.11)
- *One-Step Versus the Two-Step Biopsy Procedure for Breast Cancer* (#3420)
- *Mammography 1982—A Statement of the American Cancer Society* (#3423)
- *Different Perspective on Breast Cancer Risk Factors: Some Implications of the Nonattributable Risk* (#3430)

Colon/Rectum

- *Early Diagnosis of Colorectal Cancer* (#3311)
- *Colonoscopy and Colon Cancer: Current Clinical Practice* (#3356)
- *Proctosigmoidoscopy in Asymptomatic Men and Women* (#3417)
- *Current Status of Fecal Occult Blood Testing in Screening for Colorectal Cancer* (#3426)

Gyn

- *Statistical and Epidemiological Information on Gynecological Cancer* (#3030)
- *Detection, Diagnostic Evaluation and Treatment of Dysplasia, Carcinoma in Situ and Early Invasive Cervical Carcinoma* (#3387)

Lung

- *Lung Cancer: Current Concepts and Prospects* (#3353)
- *Lung Cancer Will Soon Be the #1 Cancer Killer of American Women* (7 ¼″ × 9 ¾″ countercard) (#3738)

Oral

- *Oral Cancer Examination Procedure* (#3026)
- *Early Diagnosis of Oral Cancer: The Erythroplastic Lesion in High Risk Sites* (#3411)

Prostate

- *What is the Best Test to Detect Prostate Cancer?* (#3303)

C. Smoking Materials for Physicians

- *Physicians' Quit Kit.* Includes 2 posters, 50 booklets each of *Quit It* and *For Good*, Quit for Good Folders, Table Tent Cards, Instructions on "How to Help Your Smokers Become Nonsmokers."
- *The Physicians' Guide: How to Help Your Hypertensive Patients Stop Smoking.* Booklet provides a step-by-step approach to help hypertensive patients stop smoking. U.S. DHHS and National Heart, Lung and Blood Institute, April 1983.
- *Cancer Prevention Research Summary: Tobacco.* Covers evidence, cancer types, numbers affected, possibilities for prevention. U.S. DHHS, NIH/NCI, February 1984.
- *Physicians' Help Quit Kit* (#3401) Included in *Help Quit Kit*: Waiting Room Sign, Desk Top Sign, Prescription Pad—Quit Smoking, Smoker's Sign—peel off label to attach to patient's file, Poster, and Patient's take-home literature.
- *Strategic Withdrawal From Cigarette Smoking* (#3412)
- *I Advise My Parents Not To Smoke* (Desk Top Sign) (#2162)
- *Tobacco and Health* (#3345)

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D. Audiovisual Materials for Physicians

The following materials are available through your local ACS Office:

Audiotapes

- *Meeting Highlights: 1980 CIS ACS National Conference on Cancer Prevention and Detection* (2 cassettes in album) (#3704)
- *Meeting Highlights: 1981 ACS/NCI National Conference on Nutrition in Cancer* (2 cassettes in album) (#3728)

Slide Sets

- *Cancer Causes and Prevention: Clues From Epidemiology* (set of 77 slides) (#3809)
- *Cancer Statistics—1984* (set of 23 slides) (#3808)
- *Colorectal Cancer* (#3805)
- *Proctosigmoidoscopy in the Physician's Office* (#3811)

Films or Videocassettes

- *Early Detection of Colorectal Cancer* (#3790)
- *Proctosigmoidoscopy in the Physician's Office* (#3793)
- *Detecting Breast Cancer Earlier* (film only (#3786)

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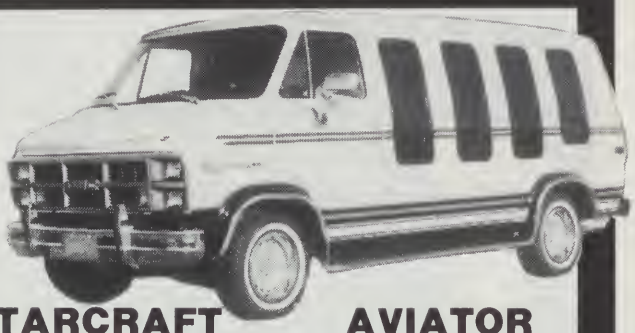
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LOCATION: University of Maryland at Baltimore

TOPICS TO BE DISCUSSED:

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Allergies & Asthma
Environmental Health Hazards
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Doctors Take Note

Miscellaneous Meetings

Jan 28–30 Consensus Development Conference on Travelers' Diarrhea. NIH Clinical Center, Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Info: M. Dillon, Prospect Associates, Suite 401, 2115 E. Jefferson St., Rockville, MD 20852 (301-468-6555)

Feb 4–6 Winter Retreat: Update on Pulmonary Disorders, presented by the Division of Pulmonary Medicine and the Office of Continuing Medical Education at the Medical College of Virginia. Fee: $250 for physicians, $135 for physicians in training and all health care professionals; 12 AMA Cat I credits; 12 prescribed hours AAFP, 1.2 CEU by Virginia Commonwealth University. Info: B Winn, Continuing Medical Education, Box 48-MCV Station, Richmond, VA 23298 (804-786-0494)

Feb 4–6 Rehabilitation of the Coronary Patient, American College of Cardiology's Learning Center, Bethesda. Fee: $375 for College members; $435 for nonmembers. 19 ACCME Cat I credits. Info: ACC. Learning Center Registrar, 9111 Old Georgetown Road, Bethesda, MD 20814 (301-897-5400, ext. 241)

Feb 11–13 Cardiology Update for Intensive Care Unit Nurses, American College of Cardiology's American Assoc of Critical-Care Nurses, 2.1 CEUs. Info: ACC, Learning Center Registrar, 9111 Old Georgetown Road, Bethesda, Md 20814 (301-897-5400, ext. 241)

Feb 11–13 Consensus Development Conference on Health Implications of Obesity. NIH, Clinical Center, Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Info: M. Dillon, Prospect Associates, Suite 401, 2115 E. Jefferson St., Rockville, MD 20852 (301-468-6555)

Feb 20–24 Third Annual Winter Continuing Medical Education Festival, sponsored by Geisinger Clinic. Pocono Hershey Resort, White Haven. Fee: $115 for physicians, $95 for students; 25 Cat I credits and workshops. Info: S. Hanley, Continuing Education Program Registrar, Geisinger Medical Center, Danville, PA 17822 (717-271-6692)

Feb 20–22 Thromboembolic and Atherosclerotic Disease—An Update on Pathogenesis, Prevention, and Treatment, American College of Cardiology's Learning Center, Bethesda. Fee: $375, for College members; $425 for nonmembers. 17.5 ACCME Cat I credits. Info: ACC, Learning Center Registrar, 9111 Old Georgetown Road, Bethesda, MD 20814 (301-897-5400, ext 241)

Feb 25–27 Cardiovascular Surgery: Coronary—Extending the Procedure: Valvular—Matching the Patient, Challenging Management Problems, American College of Cardiology's Learning Center, Bethesda. Fee: $375 for College members; $435 for nonmembers. 17 ACCME Cat I credits. Info: ACC, Learning Center Registrar, 911 Old Georgetown Road, Bethesda, MD 20814 (301-897-5400, ext. 241)

Mar 13 Antarctica. CME topic of the American Medical Women's Association. Meeting held at the Johns Hopkins Faculty Club, Homewood Campus; cash bar at 6:30 p.m.; dinner at 7 p.m.

Apr 25–28 Annual Meeting, The Virginia Society of Otolaryngology-Head and Neck Surgery, Tides Inn, Irvington, VA. Info: D. Strawderman, 4205 Dover Road, Richmond, VA 23221 (804-353-2721)

May 8 Disability and the Social Security Administration. CME topic of the American Medical Women's Association. Meeting held at the Johns Hopkins Faculty Club, Homewood Campus; cash bar at 6:30 p.m.; dinner at 7 p.m.

May 8–11 Annual Meeting, The Virginia Society of Ophthalmology, Boar's Head Inn, Charlottesville, VA. Cosponsored by University of Virginia Ophthalmology Dept. Info: D. Strawderman, 4205 Dover Road, Richmond, VA 23221 (804-353-2721)

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Taylor Manor Hospital CME Lectures

All lectures at 3 p.m. in the Psychiatric Center at Taylor Manor Hospital, Ellicott City, MD unless otherwise indicated. Info: Taylor Manor Hospital, College Ave., Ellicott City, MD 21043 (301-465-3322)

Jan 23 Lithium Management of the Young Bipolar Patient: A Longitudinal Perspective

Feb 20 The Young Chronic Schizophrenic

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The Johns Hopkins Medical Institution

All courses at the Turner Auditorium Building unless otherwise indicated. Sponsored Continued Education Activities for 1984–85. Info: Office of Continuing Education, 720 Rutland Ave., Turner Auditorium, Baltimore, MD 21205 (301-955-5880).

Jan 25 Symposium on Ocular Melanoma, sponsored by the Wilmer Institute. Fee: $120; 8 AMA Cat I credits. Contact: P. Nulle (301-955-6046).

Feb 28–Mar 3 Computed Body Tomography 1985—The Cutting Edge, sponsored by the Johns Hopkins University School of Medicine, held at Fort Lauderdale, FL. Fees: $250 ($175, residents and fellows with letter); 21 AMA Cat I credits.

Mar 14–15 Quantitative Imaging of Neuroreceptors in the Human Brain. Fee: $200; Cat I AMA credits, Psychology CEUs. Info: A. Kearney, Program Coordinator (301-955-6046)

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The Department of Radiology and Radiological Science, offers several courses in abdominal and obstetrical ultrasound: courses scheduled Jan 14 to Dec 6, 1985. Info: Joan Mosmiller, Department of Radiology (301-955-8450)

Basic Practicum—Mar 11–15; Jun 3–7; Aug 5–9; Sep 23–27. Fee: $460; 40 AMA Cat I credits

Advanced Practicum—May 13–17; Dec 2–6. Fee $460; 40 AMA Cat I credits

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Clinical Cytopathology for Pathologists, 1985 Postgraduate Institute: March to May 1985, Home Study Course A; **May 6–17,** In-Residence Course B at the Johns Hopkins Medical Institution, Baltimore. Designed solely for pathologists who are Certified (or qualified for certification) by the American Board of Pathology or its international equivalent, this is an intensive refresher in all aspects of the field of Clinical Cytopathology. Topics are covered in lectures, in small informal conferences, and over the microscope. Self-instructional material is available. Loan set of slides with texts (Course A) will be sent to each participant within the U.S. and Canada for home study during March and April before Course B in Baltimore. Special arrangements to study Course A must be made by participants outside the U.S. and Canada. 152 AMA Cat I credits. *The entire course given in English.*

Completed preregistration must be accomplished before **April 5, 1985,** unless by special arrangement. Info: John K. Frost, MD, 604 Pathology, Bldg., The Johns Hopkins Hospital, Baltimore, MD 21205, USA

University of Maryland School of Medicine

CME Courses: For each course additional information may be obtained by contacting Program of Continuing Education, University of Maryland School of Medicine, Room 300, MSTF, 10 South Pine St., Baltimore, MD 21201 (301-528-3956)

Jan 4–23 Animal Agents and Vectors of Human Diseases. 22 AMA Cat I credits

Feb 7–May 14 Advanced Immunology. 15 AMA Cat I credits. Info: 301-528-7110

Feb 21–Mar 28 Selected Topics in Family Practice: Spring Series, Baltimore. Fee $100, 15 AMA Cat I credits

Mar 24–29 Fifth Annual Postgraduate Course in Neurological Disorders: Stroke and Tumors, Paradise Island, The Bahamas. Fee: $425; 25 AMA Cat I credits.

Apr 12–13 First Annual University of Maryland Contact Lens Symposium. Columbia Inn. Fee: $165; 11.5 AMA Cat I credits.

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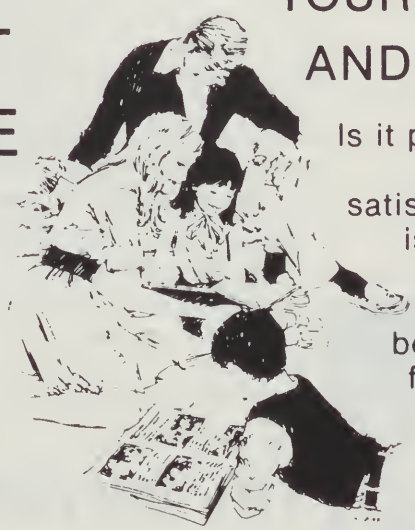
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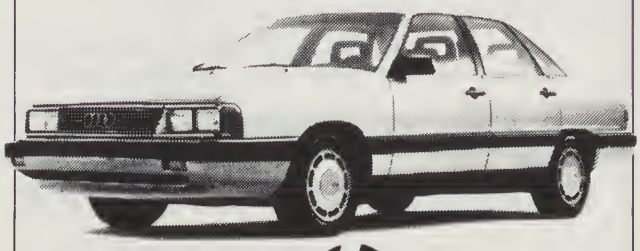
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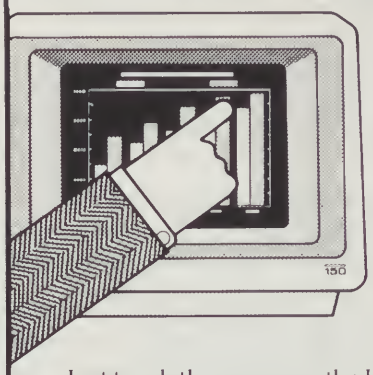


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Victor Boehm Bldg. Co. 49
Bonnie Ridge Apartments 11
Bon Secours Hospital 99
Bon Secours Professional Center 16
Business Automation, Inc. 93
Campbell Laboratories 12
Campus Books, Inc. 15
Creative Health Seminar Consultants 94, 97
Curtis 1000 Information Systems 25
CTS 27
Eastman Kodak 21
Elkridge Estates 43
Executive Billing Associates 55
Family Home Care 101
Family Recovery Center 70
Franklin Square Hospital 92
Freestate Management Co. 26
GMC Truck 92
I. Elliott Goldberg, Attorney 92
Gordon & Heneson PA 70
Heron Harbour Isle 19
Hidden Brook Treatment Center 28
Jerry's Toyota 5
King's Grant 2
Joel R. Kruh Esq. 98
Lewis Medical Instruments 24
Eli Lilly 29
Marion Laboratories 35
Maryland Medical Laboratory 1
Maryland Office Systems 100
Medical Mutual Liability . . . . . cover 2
MEDICLINICS 26
Michaelson Motors, Inc. 76
MICRO Age 12
Miller Studio 49
Montrose and Associates 98
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Earl S. Oxley, CPA 62, 97
W.C. Pinkard 70
PM Baltimore 66
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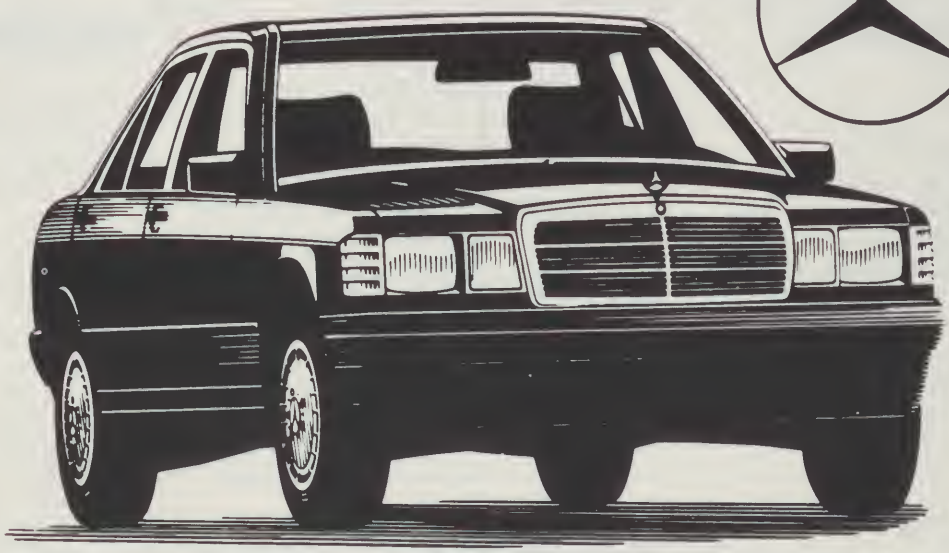
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February 1985

MMJ
Maryland Medical Journal

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ARTICLES

Osteoarthritis V: Medical Management—Thomas M. Zizic MD . . . 147

Miliary Tuberculosis Masquerading as Late Infection in Total Hip Replacement—Michael L. Levin MD . . . 153

Supervision of the Impaired Physician in a Clinical Practice Setting—James P.G. Flynn MD . . . 161

Current Approach to PID—Norman Levin MD . . . 163

Health Care Costs—Past, Present, and Future—John Meyerhoff MD . . . 167

DEPARTMENTS

Annual Meeting Announcements . . . 108

Book Review . . . 114

The Library Page . . . 128

Disease Control and Epidemiology Newsletter . . . 133

High Blood Pressure Commentary . . . 142

One Minute with Diabetes . . . 145

Inside Med-Chi . . . 175

Discipline Commission Action . . . 180

Call for Papers/Photo Contest . . . 193

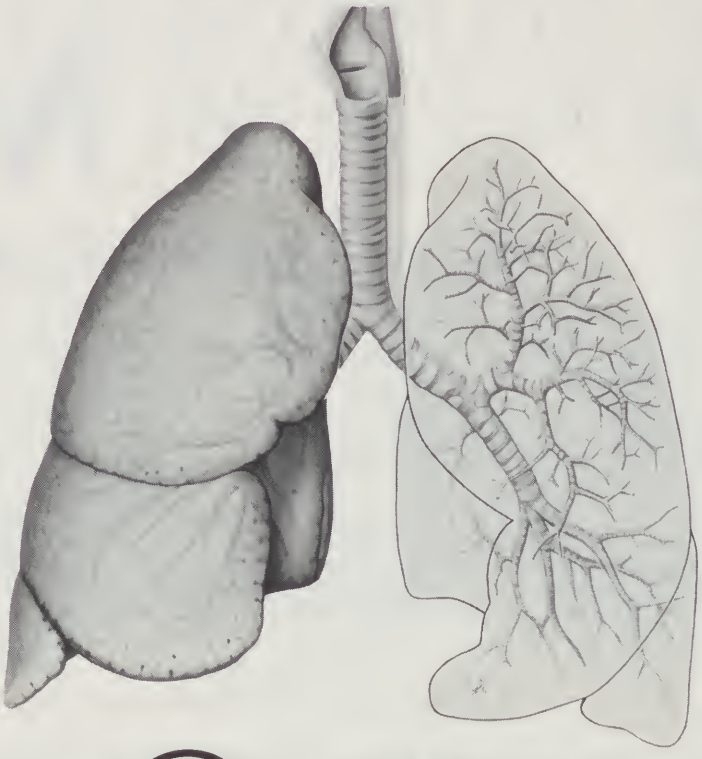
MISCELLANY

Medical Miscellany . . . 115
Executive Director's Newsletter . . . 119
Hotline Numbers . . . 144, 182
Members in the News . . . 190
Physician Placement Service . . . 191
Doctors Take Note . . . 194
Medicolegal Hotline . . . 195
T-Shirt Order Form . . . 196
Classified Ads . . . 199
Advertisers' Index . . . 201

On the cover: Bassist Owen Cummings, of the Baltimore Symphony Orchestra, is a double bass instructor at Towson State University. The Library Page, reporting on the Biology of Music Making Conference, begins on page 128. Photo by J. Jensen.

The views in this publication are those of the authors and do not necessarily reflect the opinion of the Medical and Chirurgical Faculty of the State of Maryland.

Consider the causative organisms...



Ceclor®
cefaclor
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offers effectiveness against the major causes of bacterial bronchitis

H. influenzae, *H. influenzae*, *S. pneumoniae*, *S. pyogenes*
(ampicillin-susceptible) (ampicillin-resistant)

Brief Summary. Consult the package literature for prescribing information.

Indications and Usage: Ceclor* (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae)*, *Haemophilus influenzae*, and *S. pyogenes* (group A beta-hemolytic streptococci)

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor

Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out

Precautions: *General Precautions* — If an allergic reaction to Ceclor* (cefaclor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy — Pregnancy Category B — Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor* (cefaclor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed

Nursing Mothers — Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Ceclor is administered to a nursing woman.

Usage in Children — Safety and effectiveness of this product for use in infants less than one month of age have not been established

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below.

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbiliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic — Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic — Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal — Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200)

[0617B2R]

Note: Ceclor* (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information

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187th ANNUAL MEETING

Thursday–Saturday, April 25–27, 1985

HUNT VALLEY INN, HUNT VALLEY, MARYLAND

THURSDAY, APRIL 25, 1985

8:30 a.m.
COUNCIL

9:30 a.m.
HOUSE OF DELEGATES
All members are invited to attend.

8:45 a.m.
LEGISLATION POLICY WITH REGARD TO PHYSICIAN ASSISTANTS, **F. Lynn May,** Arlington, VA and **Curtis Decker,** Annapolis

PRESENT UTILIZATION OF PHYSICIAN ASSISTANTS
Education and Training, Robert Solomon PA-C, Baltimore; **Surgical Physician Assistants, Jeffrey Stark PA-C,** Baltimore; **Physician Assistants Used as Medical Housestaff, Bernard Tabatznik MD,** Baltimore; **Emergency Room Physician Assistants, Wayne S. Barry MD,** Baltimore;

FUTURE ROLE OF PHYSICIAN ASSISTANTS IN THE HEALTH CARE DELIVERY SYSTEM, **James Cawley PA,** Washington DC, **Karl Katterjohn PA-C,** Baltimore and **Gretchen Shafft PhD,** Baltimore, Maryland Academy of Physician Assistants

12:15 p.m.
PRAYER LUNCHEON
Pastoral Care: Profession, Plebeian Career, or Placebo? The Reverend Grady F. W. Barbour, Linthicum, Committee on Medicine and Religion/Med-Chi

1:00 p.m.
The Field Liaison for the American College of Surgeons Meeting—All Liaison Fellows and Associate Fellows are Invited to Attend

2:00 p.m.
DEALING WITH THE SOMATIZING PATIENT
Somatization: Diagnosis and Management, Charles V. Ford MD, Nashville, TN; **Somatization: Impact Upon the Patient's Family, Lee Randol Barker MD,** Baltimore, The Maryland Psychiatric Society, Inc.

Emotional Development in the First Eighteen Months: Principles of Intervention and Clinical Diagnosis in Infancy, Serena Wieder PhD, Silver Spring, Maryland Chapter, American Academy of Pediatrics/Infant, Child & Adolescent Health Subcommittee/Med-Chi

Introductory Remarks, Paul Bormel MD, Baltimore; **Joseph S. McLaughlin MD,** Baltimore—**Moderator; Pancreatic Transplantation, Frederick R. Bentley MD,** Baltimore; **Breast Reconstruction After Mastectomy—Immediate versus Delayed, Nelson H. Goldberg MD,** Baltimore; **Application of the Laser to Surgery, William C. Gray MD,** Baltimore, Maryland Chapter, American College of Surgeons

Aneurysmal Subarachnoid Hemorrhage—An Update, Harold P. Adams, Jr. MD, Iowa City, IA, American Heart Association, Maryland Affiliate/Stroke Working Group

The Role of Food Hypersensitivity and Atopic Dermatitis, Hugh A. Sampson MD, Durham, NC, Maryland Asthma and Allergy Society

Endoscopy Update 1985, David Fleischer MD, Washington DC, Maryland Society of Gastrointestinal Endoscopy

Keeping the Elderly Functional and Fit, Franz U. Steinberg MD, St. Louis, MO, Maryland Society of Physical Medicine and Rehabilitation

EFFECTIVE COMMUNICATION CAN REDUCE YOUR RISKS OF MEDICAL LIABILITY, **Marlyn D. Boyd PhD,** Columbia, SC and **Allen Douma MD,** Washington DC, Center for Health Education

4:00 p.m.
PLENARY SESSION
THE CHALLENGE OF CHANGE, **Paul M. Ellwood, Jr. MD,** Excelsior, MN

FRIDAY, APRIL 26, 1985

8:45 a.m.
BREAKFAST AND LEARN

FUTURE PERSPECTIVES OF OTOLARYNGOLOGY—HEAD AND NECK SURGERY
Richard R. Gacek MD Syracuse, NY, Maryland Society of Otolaryngology—Head and Neck Surgery

HELPING YOUR PATIENTS CONTROL THEIR BLOOD LIPIDS
Introduction, Frank Franklin MD, Baltimore; **When and How to Evaluate a Patient's Lipids, Thomas Pearson MD,** Baltimore; **What Can be Learned from a Family History & Apoprotein Measurements, Peter Kwiterovich MD,** Baltimore; **What Diet Should I Recommend? Frank Franklin MD;** Questions and Answers

Break

Introduction, Frank Franklin MD, Baltimore; **How to Help Patients Change Habits and Lose Weight, Kelly Bronwell PhD,** Philadelphia, PA; **Positive and Negative Aspects of Exercise Training: How to Start and Maintain Patients in an Exercise Program, Andrew Goldberg MD,** Baltimore; **How to Help Patients to Stay on Diets in Everyday Life, Ginny Hartmuller MS,** Baltimore; **When and How to Begin Lipid Lowering Medications, Simeon Margolis MD,** Baltimore, American Heart Association, Maryland Affiliate, Inc.

Respiratory Failure and Chronic Obstructive Pulmonary Disease, Peter Terry MD, Baltimore; **Emphysema, Pathogenesis and Future Therapy, Ronald G. Crystal MD,** Bethesda, Maryland Thoracic Society

3rd Annual Meeting of the Directors of Medical Education, Continuing Medical Education Review Committee/Med-Chi

Topic to be Announced, William R. Irby MD, Richmond, VA, Maryland Society for the Rheumatic Diseases/Pfizer Laboratories

10:45 a.m.
The Challenge of Change: Governmental and Socioeconomic Changes in the Health Field, Peyton E. Weary MD, Charlottesville, VA, Maryland Dermatologic Society

Tissue Expanders, John B. McCraw MD, Norfolk, VA, The John Staige Davis Society of Plastic Surgeons of Maryland

THE PHYSICIAN, HIS PATIENT, AND THE WORKPLACE
Post-Coronary By-Pass Patients: Their Ability to Return to Work, Phillip Achuff MD, Baltimore; **Radiology's Role in the Diagnosis of Abestosis, Paul S. Wheeler MD,** Baltimore; **Prescription Medicines: How They Affect the Ability to Work, Michael Spodak MD,** Baltimore, Maryland Occupational Medical Association/Occupational Health Committee/Med-Chi

Legal and Ethical Issues in the Termination of Treatment, Neal M. Friedlander MD, Baltimore, Maryland Lung Association of Maryland

Topic to be Announced, Kenneth H. Williams MD, Ft. Washington, PA, Committee on Physician Rehabilitation/Committee on Alcoholism/Med-Chi

12:15 p.m.
LUNCH AND LEARN

2:00 p.m.
UPDATE ON HIGH BLOOD PRESSURE: 1985
New Drugs and Old Favorites: What to Choose, Ray W. Gifford Jr. MD, Cleveland, OH; **The Five-Hour Office Blood Pressure Check: An Alternative to Hospitalization, Lee Randol Barker MD,** Baltimore; **The New Division of Hypertension: The University of Maryland School of Medicine, Elijah Saunders MD,** Baltimore; **The Role of Calcium, Sodium, and Other Nutrients in Blood Pressure Regulation, Michael J. Horan MD,** Bethesda; **The Systolic Hypertension in the Elderly Program (SHEP), Roger Sherwin MD,** Baltimore; **JNC III: Changes in HBP Referral and Guidelines, Donald O. Fedder DrPH,** Baltimore, Maryland High Blood Pressure Commission

RESOLVING AND AVOIDING MEDICAL STAFF CONFLICTS IN MULTI-SPECIALTY HOSPITALS: A MARKETING APPROACH, **Andrew P. Morley MD,** Decatur, GA and **Ellen J. Belzer,** Kansas City, MO, Maryland Academy of Family Physicians

SPOUSE ABUSE—**Honorable Martha Wyatt,** Annapolis—**Moderator**
Domestic Violence, Honorable John J. Bishop Jr., Towson; **Legal Resources Available to Battered Spouses, L. Tracy Brown, Esquire,** Baltimore; **Why Does She Stay? Harriet Douglas LCSW,** Annapolis; **Medical Aspects of Domestic Violence, Bruce L. Regan MD,** Baltimore; **Clinical Research on Consequences of Criminal Sanctions for Domestic Violence: Implications for Medical Practice and Ethics, Lawrence W. Sherman PhD,** College Park, Office of the Attorney General for the State of Maryland/Med-Chi

DEMONSTRATION OF A MEDICOLEGAL TRIAL INVOLVING TRAUMATIC CHRONIC PAIN SYNDROME
Elliott Fishel MD, Medical Moderator—**H. Albert Korn, Esquire,** Legal Moderator

Physicians
Don M. Long MD, Baltimore, **Paul McAffee MD,** Baltimore, **Godfrey Pearlson MD,** Baltimore, **David Conblath MD,** Baltimore

Judges
The Honorable Robert L. Karwacki, Annapolis, **The Honorable John P. Corderman,** Washington County, **The Honorable John F. McAuliffe,** Montgomery County

Attorneys
Charles M. Tobin, Esquire, Montgomery County, **Stuart M. Salsbury, Esquire,** Baltimore, **John E. Sandbower III Esquire,** Baltimore, **Patti G. Zimmerman, Esquire,** Baltimore, **George J. Goldsborough Jr., Esquire,** Talbot County

Critique
Elliott Fishel MD
William G. Speed III MD
Medicolegal Committee/Med-Chi

Changing Gears to Meet the Challenge of the Geriatric Imperative, William R. Hazzard MD, Baltimore Long Term Care and Geriatrics Committee/Med-Chi

Challenges In Choosing the Best Treatment for the Emotionally Disturbed Adolescent, Jay LeBow MD, Ellicott City, Taylor Manor Hospital

Quality, Technology and Malpractice: Are We Victims of Our Own Devices? William F. Jessee MD, Chapel Hill, NC, Medical Mutual Liability Insurance Society of Maryland

THE HORIZONS OF CHANGE IN ORTHOPEDICS
New Concepts in the Diagnosis and Treatment of Wrist Injuries, Gaylord L. Clark MD, Baltimore; **Michael McClinton MD** Baltimore; **Over the Orthopedic Rainbow, John Gordon MD,** Baltimore, Maryland Orthopaedic Society

4:00 p.m.
Smoking—the #1 Health Problem, Edward N. Brandt Jr. MD, Baltimore, Committee on Preventive Medicine and Public Health/Med-Chi

Acute Post-Operative Hypertension, Leigh Thompson MD, Indianapolis, IN, Maryland-DC Society of Anesthesiologists

APPROACH TO SWALLOWING PROBLEMS: A PANEL DISCUSSION
Neurology, David W. Bucholz MD, Baltimore; **Radiology, Martin W. Donner MD,** Baltimore; **Otolaryngology, Haskins Nashima MD,** Baltimore; **Gastroenterology, William J. Ravich MD, Rehabilitation Medicine, Arthur Siebens MD,** Baltimore, The Johns Hopkins Swallowing Clinic

Bone Imaging in the Study of Pleasure and Pain, Lawrence E. Holder MD, Baltimore, Maryland Society of Nuclear Medicine
Maryland Society of Eye Physicians and Surgeons

SATURDAY, APRIL 27, 1985

8:30 a.m.
Ovarian Echos, Peter L. Cooperberg MD, Vancouver, Canada; **Fetal Intervention, David Graham MD,** Rochester, NY, Maryland Radiological Society/ Obstetrical and Gynecological Society of Maryland

8:45 a.m.
Changing Concepts in Pathology—With Particular Emphasis on Urological Pathology, Fathollah K. Mostofi MD, Washington DC, Maryland Society of Pathologists

PRO: How Will it Affect Your Patients, Everet F. Bryant, Philadelphia, PA; **Leon Kassel MD,** Baltimore; **Bert Harrell,** Baltimore, Public Relations Committee/ Med-Chi

10:45 a.m.
PLENARY SESSION
PHYSICIANS AND THEIR FAMILIES
Commonly Encountered Problems in the Families of Physicians, William L. Webb Jr. MD, Baltimore

Panel:
J. D. Drinkard MD, Moderator
Sexual Problems, Emile A. Bendit MD, Baltimore
Issues of Substance Abuse, Sheldon I. Miller MD, Baltimore
Depression and Anxiety, Dean Schuyler MD, Baltimore Sheppard and Enoch Pratt Hospital

12:30 p.m.
MMPAC LUNCHEON
Year of the Doctor: Winners or Losers? The Honorable Larry Young, Chairman House Environmental Matters Committee, Maryland General Assembly

2:00 p.m.
House of Delegates

7:30 p.m.
Presidential Reception and Banquet



Are you concerned about radical changes now under way in the health industry?

Paul M. Ellwood, Jr., MD, President of Interstudy, Inc., will discuss the changes reshaping the health system and the forces behind these changes, describe the medical care firm of the future, and suggest ways for physicians to respond to change during a plenary session, "The Challenge of Change," at the 187th Annual Meeting of the Medical and Chirurgical Faculty of the State of Maryland. The plenary session will be held on April 25, 1985 from 4:00 to 5:30 P.M. at the Hunt Valley Inn.

Dr. Ellwood, a graduate of Stanford University Medical School, is an experienced practicing physician, medical school professor, rehabilitation center administrator, and influential advisor to top policy members in medicine, government, and business.

Dr. Ellwood devised the competitive approach to health delivery reform in the late 1960s. He brought the idea of price competition between health plans (such as health maintenance organizations) to the public's attention and was instrumental in winning government support for a variety of alternative health care delivery systems. Dr. Ellwood more recently contributed to the development of preferred provider organizations and created the MeSH approach to hospital-physician joint ventures. During the plenary session, Dr. Ellwood will focus on the role that competition is playing in reshaping medical care and how it will affect Maryland physicians.

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Everyone who makes a reservation for a meal function is preregistered for the meeting. Please pick up your registration packet which will include your badge, all tickets you have requested, and other pertinent material for the meeting, at the Advance Registration Desk, Rear of the Exhibit Hall, Valley Ballroom, Lower Level, Hunt Valley Inn. **TICKETS WILL NOT BE MAILED.**

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Sat., April 27—12:30 PM
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(If you are a Sustaining member, one ticket will be free. Remember, Sustaining Members are those who pay an additional amount beyond the regular MMPAC dues)

____**PRESIDENTIAL RECEPTION & BANQUET** $____
Sat., April 27—7:30 PM
If you wish to be seated with specific individuals, please indicate on a separate sheet and attach
$40.00 per person

TOTAL AMOUNT ENCLOSED $____

FRIDAY, 8:45-10:15 AM

BREAKFAST AND LEARN

1B. Current Treatment of Epilepsy
Gregory K. Bergey MD, Assistant Professor of Neurology and Physiology, University of Maryland School of Medicine

2B. Biofeedback and Management of Stress Incontinence
Kathryn Larsen Burgio PhD, Senior Staff Fellow, Gerontology Research Center, National Institute on Aging, Francis Scott Key Medical Center

3B. Management of the Frail Geriatric Patient Who is Home Bound
John R. Burton MD, Director, Division of Geriatric Medicine, Francis Scott Key Medical Center

4B. Update on Shock Trauma
Ameen Ramzy MD, M.I.E.M.S.S.

5B. Prenatal Diagnosis of Genetic Disease
Maimon M. Cohen PhD, Professor of Obstetrics & Gynecology and Pediatrics, University of Maryland School of Medicine; Division of Human Genetics, University of Maryland Hospital

6B. Sensible Management of Anemias
C. Lockard Conley MD, Distinguished Service Professor of Medicine, Emeritus, The Johns Hopkins University School of Medicine

7B. Update on Menopause
Gay Guzinski MD, Director, Division of Gynecology, University of Maryland Hospital

8B. Hepatitis Update
Frank L. Iber MD, Professor of Medicine, University of Maryland School of Medicine, Chief, Division of Gastroenterology, University of Maryland Hospital and Baltimore Veterans Administration Medical Center

9B. Commission on Medical Discipline
Hilary T. O'Herlihy MD FACC FCCP, Chairman of the Commission on Medical Discipline

10B. Status of Abortions in Maryland
J. Courtland Robinson MD, Medical Director, Planned Parenthood of Maryland

11B. PPO's
David M. Soloman MD

12B. Update on Migraine
William G. Speed III MD FACP, Associate Professor of Medicine, The Johns Hopkins School of Medicine

FRIDAY, 12:15-1:45 PM

LUNCH AND LEARN

13L. Rheumatic Diseases and Anti-Inflammatory Drugs
Lynn Billingsly MD, Instructor of Medicine, Division of Rheumatology, The Johns Hopkins University School of Medicine

14L. Update on AIDS
Frank M. Calia MD, Professor and Vice Chairman, Department of Medicine, University of Maryland School of Medicine; Chief, Medical Services, Baltimore Veterans Administration Medical Center

15L. Behavioral Pediatrics
Lois T. Flaherty MD, Director, Division of Child and Adolescent Psychiatry, University of Maryland Hospital

16L. Update on Acne
Ronald Goldner MD, Assistant Professor of Dermatology, University of Maryland School of Medicine

17L. Improving Surgical Care of Children
J. Alex Haller Jr. MD, Robert Garrett Professor of Pediatric Surgery, The Johns Hopkins University School of Medicine

18L. Sudden Death Cardiac Arrhythmias
John A. Kastor MD, Theodore E. Woodward Professor of Medicine, Chairman, Department of Medicine, University of Maryland School of Medicine; Physician in Chief, University of Maryland Hospital

19L. Legislative Update
Senator Francis X. Kelly, Member, Senate Budget and Taxation Committee

20L. Use of Drugs In Alcoholic Patients
Michael Potash MD, Instructor of Psychiatry, The Johns Hopkins University School of Medicine; Former Chairman, Governor's Advisory Commission of Drug Abuse

21L. Inflammatory Bowel Disease
David M. Saltzberg MD, Assistant Professor of Medicine, Division of Gastroenterology, University of Maryland School of Medicine

22L. Retirement Planning
Jacques T. Schlenger, Esquire, Managing Partner, Venable, Baetjer and Howard

23L. Sexual Abuse of Children
Charles I. Shubin MD, Chief of Pediatrics, Lutheran Hospital of Maryland, Chairman, Governor's Task Force on Child Abuse and Neglect

24L. PRO—Where it Stands and Where It May Go
Kennard Yaffe MD, Chairman, Baltimore City PSRO; Medical Director, Maryland Foundation for Health Care

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April 25–27, 1985

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SORBITRATE
(ISOSORBIDE DINITRATE)

Please consult full prescribing information before use. A summary follows:

INDICATIONS AND USAGE: SORBITRATE (isosorbide dinitrate) is indicated for the treatment and prevention of angina pectoris. All dosage forms of isosorbide dinitrate may be used prophylactically to decrease frequency and severity of anginal attacks and can be expected to decrease the need for sublingual nitroglycerin.

The sublingual and chewable forms of the drug are indicated for acute prophylaxis of angina pectoris when taken a few minutes before situations likely to provoke anginal attacks. Because of a slower onset of effect, the oral forms of isosorbide dinitrate are not indicated for acute prophylaxis.

CONTRAINDICATIONS: SORBITRATE is contraindicated in patients who have shown purported hypersensitivity or idiosyncrasy to it or other nitrates or nitrites. Epinephrine and related compounds are ineffective in reversing the severe hypotensive events associated with overdose and are contraindicated in this situation.

WARNINGS: The benefits of SORBITRATE during the early days of an acute myocardial infarction have not been established. If one elects to use organic nitrates in early infarction, hemodynamic monitoring and frequent clinical assessment should be used because of the potential deleterious effects of hypotension.

PRECAUTIONS: General: Severe hypotensive response, particularly with upright posture, may occur with even small doses of SORBITRATE. The drug should therefore be used with caution in subjects who may have blood volume depletion from diuretic therapy or in subjects who have low systolic blood pressure (eg, below 90 mmHg). Paradoxical bradycardia and increased angina pectoris may accompany nitrate-induced hypotension. Nitrate therapy may aggravate the angina caused by hypertrophic cardiomyopathy.

Marked symptomatic, orthostatic hypotension has been reported when calcium channel blockers and organic nitrates were used in combination. Dose adjustment of either class of agents may be necessary.

Tolerance to this drug and cross-tolerance to other nitrates and nitrites may occur. Tolerance to the vascular and antianginal effects of isosorbide dinitrate or nitroglycerin has been demonstrated in clinical trials, experience through occupational exposure, and in isolated tissue experiments in the laboratory. The importance of tolerance to the appropriate use of isosorbide dinitrate in the management of patients with angina pectoris has not been determined. However, one clinical trial using treadmill exercise tolerance (as an end point) found an 8-hour duration of action of oral isosorbide dinitrate following the first dose (after a 2-week placebo washout) and only a 2-hour duration of effect of the same dose after 1 week of repetitive dosing at conventional dosing intervals. On the other hand, several trials have been able to differentiate isosorbide dinitrate from placebo after 4 weeks of therapy and, in open trials, an effect seems detectable for as long as several months.

Tolerance clearly occurs in industrial workers continuously exposed to nitroglycerin. Moreover, physical dependence also occurs since chest pain, acute myocardial infarction, and even sudden death have occurred during temporary withdrawal of nitroglycerin from the workers. In clinical trials in angina patients, there are reports of anginal attacks being more easily provoked and of rebound in the hemodynamic effects soon after nitrate withdrawal. The relative importance of these observations to the routine, clinical use of isosorbide dinitrate is not known. However, it seems prudent to gradually withdraw patients from isosorbide dinitrate when the therapy is being terminated, rather than stopping the drug abruptly.

Information for Patients: Headache may occur during initial therapy with SORBITRATE. Headache is usually relieved by the use of standard headache remedies or by lowering the dose and tends to disappear after the first week or two of use.

Drug Interactions: Alcohol may enhance any marked sensitivity to the hypotensive effect of nitrates.

Isosorbide dinitrate acts directly on vascular smooth muscle; therefore, any other agent that depends on vascular smooth muscle as the final common path can be expected to have decreased or increased effect depending on the agent.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term studies in animals have been performed to evaluate the carcinogenic potential of this drug. A modified two-litter reproduction study in rats fed isosorbide dinitrate at 25 or 100 mg/kg/day did not reveal any effects on fertility or gestation or any remarkable gross pathology in any parent or offspring. Fed isosorbide dinitrate as compared with rats fed a basal-controlled diet.

Pregnancy Category C: Isosorbide dinitrate has been shown to cause a dose-related increase in embryotoxicity (increase in mummified pups) in rabbits at oral doses 35 and 150 times the maximum recommended human daily dose. There are no adequate and well-controlled studies in pregnant women. SORBITRATE should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when SORBITRATE is administered to a nursing woman.

Pediatric Use: The safety and effectiveness of SORBITRATE in children has not been established.

ADVERSE REACTIONS: Adverse reactions, particularly headache and hypotension, are dose-related. In clinical trials at various doses, the following have been observed.

Headache is the most common (reported incidence varies widely, apparently being dose-related, with an average occurrence of about 25%) adverse reaction and may be severe and persistent. Cutaneous vasodilation with flushing may occur. Transient episodes of dizziness and weakness, as well as other signs of cerebral ischemia associated with postural hypotension, may occasionally develop (the incidence of reported symptomatic hypotension ranges from 2% to 36%). An occasional individual will exhibit marked sensitivity to the hypotensive effects of nitrates and severe responses (nausea, vomiting, weakness, restlessness, pallor, perspiration, and collapse) may occur even with the usual therapeutic dose. Drug rash and/or exfoliative dermatitis may occasionally occur. Nausea and vomiting appear to be uncommon. Case reports of clinically significant methemoglobinemia are rare at conventional doses of organic nitrates. The formation of methemoglobin is dose-related and, in the case of genetic abnormalities of hemoglobin that favor methemoglobin formation, even conventional doses of organic nitrate could produce harmful concentrations of methemoglobin.

DOSAGE AND ADMINISTRATION: For the treatment of angina pectoris, the usual starting dose for sublingual SORBITRATE is 2.5 to 5 mg; for chewable tablets, 5 mg; for oral (swallowed) tablets, 5 to 20 mg, and for controlled-release forms, 40 mg.

SORBITRATE should be titrated upward until angina is relieved or side effects limit the dose. In ambulatory patients, the magnitude of the incremental dose increase should be guided by measurements of standing blood pressure.

The initial dosage of sublingual or chewable SORBITRATE for prophylactic therapy in angina pectoris patients is generally 5 or 10 mg every 2 to 3 hours. Adequate controlled clinical studies demonstrating the effectiveness of chronic maintenance therapy with these dosage forms have not been reported.

SORBITRATE in oral doses of 10 to 40 mg given every 6 hours or in oral controlled-release doses of 40 to 80 mg given every 8 to 12 hours is generally recommended. The extent to which development of tolerance should modify the dosage program has not been defined. *The oral controlled-release forms of isosorbide dinitrate should not be chewed.*

DOSAGE FORMS AVAILABLE: Sublingual Tablets (2.5, 5, 10 mg); Chewable Tablets (5, 10 mg); Oral Tablets (5, 10, 20, 30, 40 mg); Sustained Action Tablets (40 mg).

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Book Review

Atlas of Breast Reconstruction Following Mastectomy

Edited by Bernard M. McGibbon MD, FACS. Baltimore: University Park Press, 224 pages, hardcover, $65.

Dr. McGibbon has dealt effectively with a difficult subject and has enlisted the aid of several well-known surgeons in attempting to give a current overall picture of the techniques of breast reconstruction. In general, it is a well-organized book, and it covers the pertinent facets of this category of surgery.

The chapter on the philosophy of breast reconstruction is very good and, although short, the chapter on the psychiatric considerations of breast reconstruction accurately analyzes the assault to the woman's self-image that is common after a mastectomy operation. The section on preoperative evaluation and planning is truly excellent and offers a reasonable and methodical approach to the patient who is referred for breast reconstruction. On the other hand, the chapter outlining the use of the temporary tissue expander is somewhat disorganized and a bit evangelistic in its "selling" of this particular approach. Overall, in an Atlas of this type, I expected more drawings than photographs. Many of the photographs (and there are *many*) are of a quality that is not ideal, and a few are misleading in that the lighting is poor and the camera angle is faulty. In the drawings, some sequences could benefit from more detail of intraoperative dissections and thereby be more useful for interns and residents. As in the photographs, the perspective in the drawings was sometimes not ideal. However, this does not detract from the value of the book as an excellent guide to breast reconstruction.

Perhaps the best chapter is on the rectus abdominis musculocutaneous flap. This relatively new technique is well covered and well illustrated and will be of great value to those who practice breast reconstruction as well as to general surgeons who refer patients for consideration.

In summary, the *Atlas of Breast Reconstruction* is an excellent source of material on the practical management and approach to this complex subject. It will find its greatest value in its use as a ready reference for busy plastic surgeons and surgical residents who are looking for a practical guide to this type of reconstructive surgery.

ALAN E. SEYFER MD, FACS
Colonel, Medical Corps
Chief, Plastic Surgery Service

Medical Miscellany

1985 Photo Contest

The Annual Photo Contest for 1985, sponsored by the Medical and Chirurgical Faculty of Maryland, is well under way. This year's Chairman is Jerrold M. Post MD, winner of last year's contest in both the black and white and the color categories.

All members of the Faculty and its Auxiliary (except professional photographers) are invited to enter an original photo to the Faculty for judging. Each entrant may submit up to three selections in either the black and white category, the color category, or a combination of both.

All entries will be displayed and the winners announced at the Annual Meeting April 25–27, 1985. The winning photos also will be reproduced in the *Maryland Medical Journal*, and a prize related to the art of photography will be awarded to the First and Second place winners in each category.

To become a part of this year's photo competition, mail or bring your favorite photo(s) to the Med-Chi office at 1211 Cathedral Street, Baltimore, Maryland 21201 by the end of the business day on March 29, 1985.

Those entering the contest also need to be aware of the following rules:

1. All entries must have name, address, and telephone number attached to the back of each photograph.
2. PRINTS only, no smaller than 8 × 10 or larger than 11 × 14, will be accepted (slides must be converted to prints within this size range).
3. Entries MUST be matted or dry mounted—no framed photographs accepted.
4. Photographs will NOT be mailed back—photographs may be claimed at the exhibit area at the close of the Annual Meeting on Saturday, April 27 at noon or at the Faculty Building thereafter.
5. Med-Chi does not guarantee against loss or damage of any kind to the photographs submitted to the contest.

For further information, contact Diane Sakwa at Med-Chi 301-539-0872 or toll free 1-800-492-1056.

Public Relations/Membership Coordinator

Nina C. Casey recently joined Med-Chi as Public Relations/Membership Coordinator. Her responsibilities include implementation of the membership development program and coordination of public relations projects. She also will assist in coordination of the Maryland Tel-Med Program and staff the Public Relations Committee.

Casey comes to Med-Chi from Washington College in Chestertown, Maryland, where she earned her bachelor's degree in English.



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AMA's Survey Opinon and Briefs

Patient Education, PMIs, and Physician Opinion

In 1982 the AMA launched a program to distribute pads of Patient Medication Instructions (PMIs) to physicians for use in counseling patients on proper drug use. As the program developed, there became a need to examine opinions of physicians on the issue of patient education in general, and to measure their reactions to actual PMI use.

To meet this need, the Association commissioned a survey of physician opinion in late June 1983. Data presented here are based on 1,000 telephone interviews with physicians selected at random from a population of physicians who are likely to prescribe the drugs covered by the 40 different PMI sheets.

Views Toward Patient Education: Pro

Results show strong support among physicians for increased patient education. This support is due to perceived effects of education on *costs*, *effectiveness*, the physician-patient *relationship*, and *callbacks* to the office.

"There is a real need for patients to become better educated about their health."	Agree	95 percent
	Disagree	3 percent
"Increasing patient education will help control the cost of medical care by reducing unnecessary visits to physicians."	Agree	86 percent
	Disagree	16 percent
"Giving patients more information on treatment will improve the *effectiveness* of that treatment."	Agree	88 percent
	Disagree	8 percent
"Giving patients written instructions about drug use interferes with the doctor-patient relationship."	Agree	11 percent
	Disagree	86 percent
"Giving written instructions for drug use will decrease unnecessary callbacks to my office."	Agree	73 percent
	Disagree	23 percent

Views Toward Patient Education: Con

From a marketing perspective, it is useful to consider aspects of patient education or PMI use that a sizable number of physicians view negatively. These include time consumption, information overload, incomplete information, convenience, and conflicting information.

"Patient education is time consuming."	Agree	81 percent
	Disagree	17 percent
"Patients can easily become overloaded with information."	Agree	71 percent
	Disagree	25 percent
"Patients with partial or incomplete information pose problems to effective treatment."	Agree	93 percent
	Disagree	4 percent
"Patient education is inconvenient."	Agree	29 percent
	Disagree	69 percent
"There is already too much health information available to patients in the popular media."	Agree	36 percent
	Disagree	58 percent

Evaluation of PMI Use

Physicians who had ordered PMIs were asked to evaluate their use.

"Would you say the PMI pads have been very useful, somewhat useful, not useful to you and your patients?"	Very Useful	28 percent
	Somewhat Useful	48 percent
	Not Useful	5 percent
	Don't Know	20 percent

"Do you think PMIs will increase or decrease?"

	Increase	Decrease	No Effect
Patient compliance with instructions	70 percent	3 percent	15 percent
Patient satisfaction with visit	71 percent	3 percent	15 percent
Your risk of malpractice claims	5 percent	50 percent	32 percent
Patients' fears about side effects	47 percent	29 percent	12 percent
Follow-up calls to verify instructions	26 percent	49 percent	14 percent

In general, physicians show strong support for improved patient education. Increased education is viewed as having positive effects on cost containment, the effectiveness of treatment, the physician-patient relationship, and unnecessary callbacks to the office.

Many of the more negative reactions are addressed directly by characteristics of the PMIs themselves, and therefore, can be used to develop marketing strategies. For example, promotional materials should stress time saving, the simplicity of information, completeness, and convenience of use.

Finally, evaluation of PMIs by physicians who have ordered pads is very positive. Some concerns about increasing patients' fears of side effects emerge. However, stressing the *balanced* approach to side effects in PMI language should ease these apprehensions.

If you have questions or want further information, contact Larry J. Freshnock PhD, Director, Survey and Opinion Research 312-751-6452.

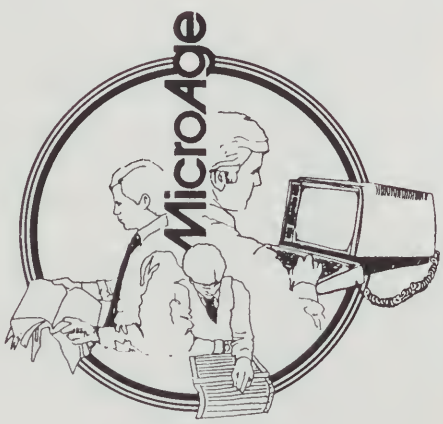
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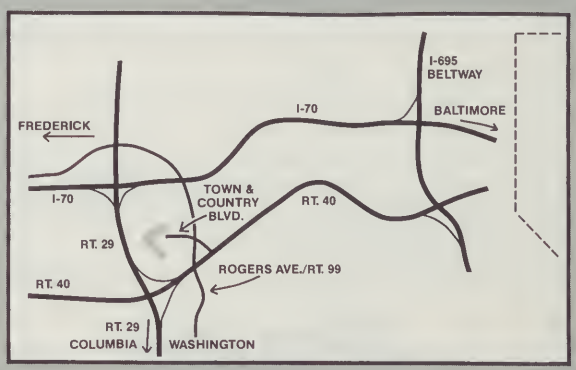


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Executive Director's Newsletter

February 1985

LEGISLATIVE PACKAGE

Mid-February will see the beginning of hearings on the Governor's Task Force on Health Care Cost Containment legislative package. The 36 initiatives of the Task Force have been distilled into seven bills including: State Affordability Limit (revenue cap), Certificate of Need for Medical Equipment in Physician Offices, Health Resources Planning Commission - Certificate of Need Suspension, Health Insurance - Limitations on PPOs, Hospital Closures, Mergers and Consolidations, Utilization Review, and Certificate of Need Moratorium.

Certificate of Need for Equipment in Physician Offices also has been addressed by a number of other bills in both houses of the General Assembly. Absent from the Task Force package, but introduced separately, is the traditional bill to include the services of radiologists, pathologists, and anesthesiologists under the Health Services Cost Review Commission.

Specific bills are available upon request from the Faculty office.

RESOLUTIONS DEADLINE

The deadline date for receipt of resolutions for consideration at the 1985 annual session of the House of Delegates is

FRIDAY, MARCH 1, 1985

At this writing, no resolutions have been received. Resolutions must be sponsored by a member or component society of the Faculty, the Council, or committees of the Faculty. A resolution introduced by an individual member must have the endorsement of either one-third of the membership of his component society or 30 members of his component society, whichever is smaller.

PRO COMPLICATIONS

The Faculty's Council urges all members to notify the Faculty office of any patient complications that arise from the implementation of the new PRO regulations. These notices will be referred to the Faculty's Committee on Utilization and Quality Control Peer Review, which is charged with reviewing the Maryland Foundation for Health Care activities in this regard.

Details, including patient's name and pertinent information, should be in writing.

PLEASE NOTE

The Maryland Foundation for Health Care, now located at 60 W. Chesapeake Avenue, Suite 608, Towson, MD 21204, has changed its phone number to 337-7400.

HOSPITAL SURVEYS

Maryland hospitals scheduled for survey by the JCAH (Joint Commission on Accreditation of Hospitals) during the month of March, 1985 are

Church Hospital, Baltimore
Sinai Hospital, Baltimore
South Baltimore General Hospital, Baltimore
Suburban Hospital, Bethesda
Union Hospital of Cecil County, Elkton
Fallston General Hospital, Fallston
V A Medical Center, Fort Howard

Prior to their visit, the Commission would appreciate receiving information relative to any problem situations in the hospital. This information will be significant in conducting an in-depth and will be maintained on a confidential basis.

PHOTO CONTEST

You are invited to submit black-and-white and color photographs to the Fifth Annual Med-Chi Photo Contest. Deadline for submission is March 27, 1985. More details are listed on page 193

ANNUAL MEETING

"Challenge of Change," the theme of the 1985 Annual Meeting, is the topic of the plenary session to be held THURSDAY, APRIL 25, 1985, 4:00-5:00 p.m. at the Hunt Valley Inn. Paul M. Ellwood, MD, President of InterStudy, will address the attendees on how the radical changes under way in the health industry will affect their practices and their ability to retain patients.

NEWS NOTES

Charles F. O'Donnell, MD, Towson, has been elected President of the Forum for Medical Affairs.

This group meets regularly at the Interim and Annual Meetings of the AMA House of Delegates to discuss major issues confronting the practice of medicine.

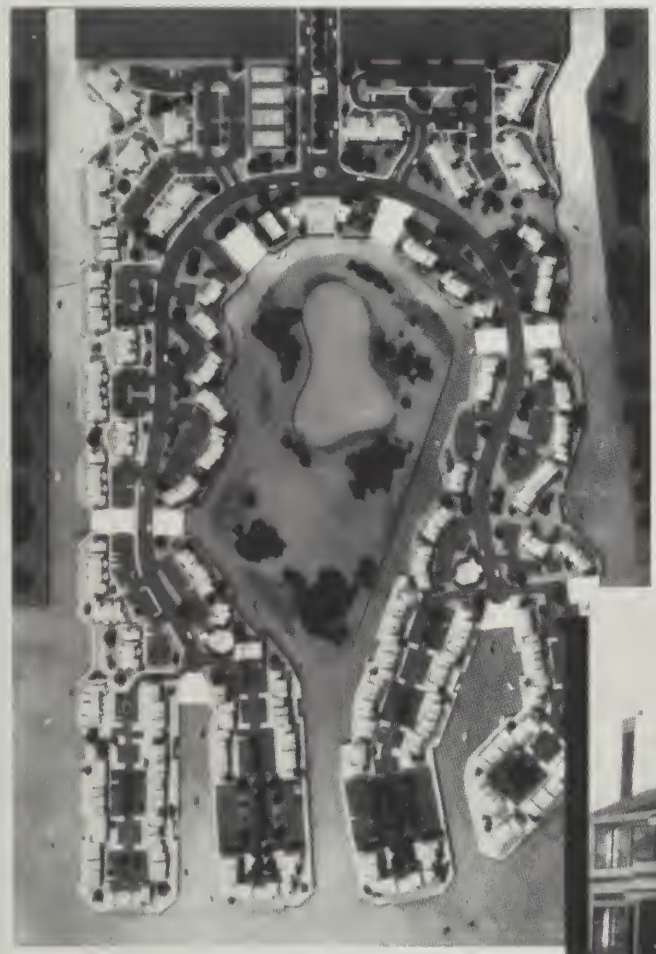
COMPENDIUM ORDERS

Response has been good to the newly published Compendium of Laws, Regulations, Opinions and Policies Governing the Practice of Medicine in Maryland. If you have not yet ordered your revised copy, I urge you to do so by using the postcard opposite this letter.

John Sargent
Executive Director

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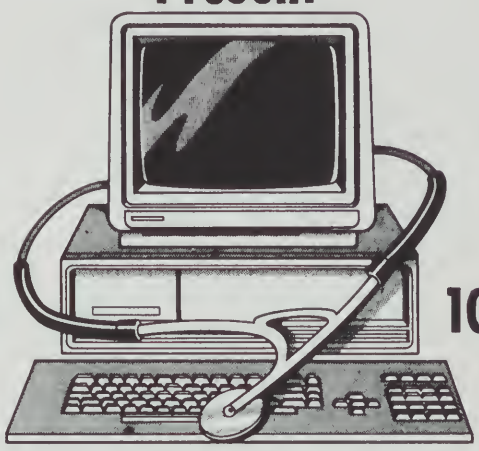
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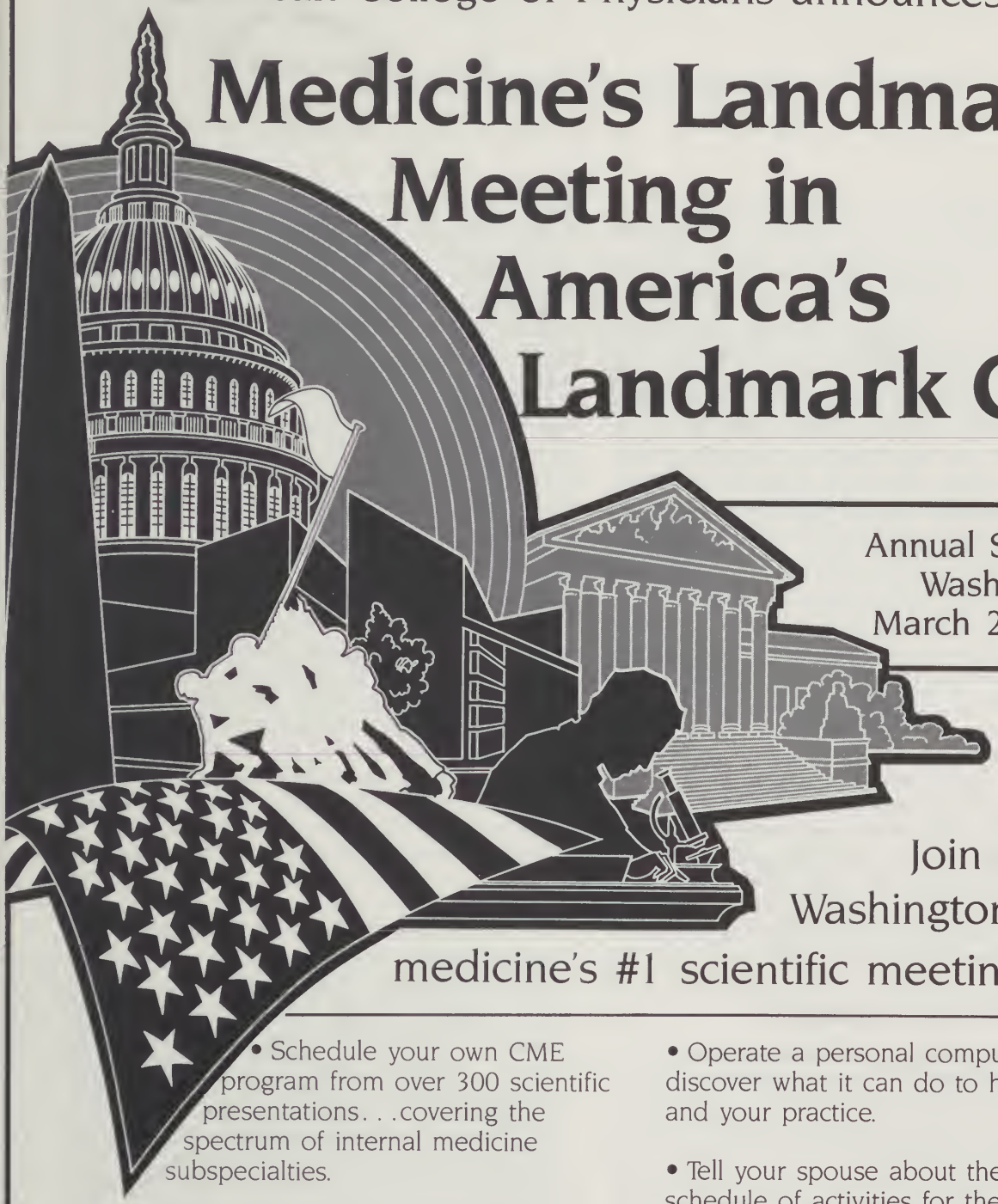
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The Library Page

The Biology of Music Making

The first Biology of Music Making Conference was held in Denver, Colorado, in July 1984. Jointly sponsored by the University of Colorado, the Denver Center for the Performing Arts, and the World Federation of Neurology, the conference was designed to explore the interrelationships of science, education, and music. There were over 400 registrants, the majority being musicians or music educators. However, approximately 20 percent of the attendees were physicians, including psychiatrists, neurologists, general surgeons, orthopedic surgeons, thoracic surgeons, internists, otolaryngologists, and others. The fields of psychology, physiology, dentistry, physics, speech pathology, biomedical engineering, biophysics, myotherapy, and music therapy also were represented. Topics discussed ranged from brain mechanisms involved in auditory perception and musical behavior, the neurology of highly skilled movements, memory, the psychological development of musicians, and performance anxiety to the experiences of tour physicians and alternative therapies for performance problems.

For this attendee, the most valuable presentations were those focusing on the occupational diseases of musicians. Three entire sessions were devoted to this problem: mechanical problems of instrumentalists, the professional voice, and the music-and-medicine panel. Each of these sessions was presented to packed crowds, including musicians suffering from various problems. The conference organizers began an informal referral system to accommodate the many performers in need of medical advice and evaluation.

Dental Problems

H. David Prensky DDS, of Florida, presented a summary of dental problems of instrumentalists. The average human swallows approximately 600 to 2,000 times a day and breathes about ten times for each swallow; these two acts must be kept separate. Proper occlusion of the mandible is crucial for this. When the mouth is at rest there should be a small space between the teeth. At present, gum disease is more of a threat to the musician's oral health than cavities. This can cause shifting teeth, loosening, bone loss, and sensitivity to temperature changes. As the teeth age, chipping and wear can be a problem. Removable shields of vinyl or wax can be used to prevent cutting the lips or oral mucosa. Even the loss of all the teeth is not the death knell once feared by instrumentalists: Bonding has replaced removable partial dentures in many cases, and this often can be done immediately. Even full dentures can be made to take playing into account. If necessary, special performance dentures that interlock in the molar area can be made. Oral implants and bone grafts are also available to solve other problems. Implants are now accepted by the American Dental Association under the proper conditions.

In childhood and adolescence, orthodontic treatment can present problems for instrumentalists. In general, such treatment is not affected by playing since most young musicians do not practice that much. However, if the musician plays a great deal, problems can result. For example, single-reed instruments such as the clarinet would exacerbate buck teeth, while a protruding lower jaw might benefit. If a person with buck teeth wants to play clarinet, a double lip embouchure similar to that employed with oboe would minimize difficulties. In any case, selection of instruments solely on the basis of their influence on malocclusions is useless. Braces often irritate the lip and mucosa of wind players of all types. Again, wax or a vinyl shield can prevent cutting. A bonus, shown in the the last several decades, is that wind instrument study can be beneficial to asthmatics.

Violin and viola players sometimes develop temporomandibular joint dysfunction with its characteristic pain, noise, and abnormal jaw movements. Squeezing down on the instrument is usually the cause, and eliminating the resulting tension is very important. Often the simplest way to do this is to rest the instrument on the clavicle rather than the shoulder itself. Muscle relaxation, surgery, and other therapies can be used.

Upper Extremity Problems

David Roos MD, University of Colorado Medical School, discussed thoracic outlet syndrome and other upper extremity problems. Many people occasionally have minor systems of thoracic outlet syndrome, such as pain, numbness, tingling, weakness of grip, and awkward movements. For the musician, the most serious problem is impairment of fine dexterity in the fingers. These symptoms can persist until they become incapacitating or threaten the person's job. They can lead to the loss of ability to perform even daily activities and cause chronic sleeplessness, intolerable pain, or even personality changes. Eventually severe complications, such as muscle atrophy, Raynaud's disease, thrombophlebitis, and embolus can result. Since thoracic outlet syndrome results from a congenital abnormality or traumatic injury to the cervical rib, collarbone, or muscle, it can usually be relieved by surgery. This operation is relatively simple and generally successful if done soon enough.

Hands

Dr. Christoph Wagner of the Institut für Experimen-

Medical and Chirurgical Faculty of the State of Maryland Library, 1211 Cathedral Street, Baltimore, MD 21201. Joseph E. Jensen, Librarian.

telle Musikpadogogik, Hochschule für Musik und Theater in Hannover, West Germany, spoke about research being done there on the shape and size of the hand, the mobility of the joints, and the strength of the muscles. There are many individual differences in normal hands, and requirements for each instrument differ. Research on pianists of all levels of achievement is only preliminary. Pianists with short fingers or tight wrists may have to take these disadvantages into account when choosing repertoire and practicing. Musicians who are unable to play fast may have high joint resistance. Some forms of performance anxiety may be biomechanically based. Extensive profiles of the hands of numerous pianists indicate that biomechanical advantages do not insure success. More importantly, biomechanical disadvantages, such as lack of passive flexibility, can lead to injuries if not recognized.

Jonathan Newmark MD reported on the work done by Fred Hochberg MD and his associates at Massachusetts General Hospital in treating musicians with hand difficulties. Their clinic has seen approximately 468 patients, falling into roughly five diagnostic groups: inflammatory disorders such as tendinitis, orthopedic dysfunction, peripheral nerve disorders such as carpal tunnel syndrome, acquired dystonias, and a miscellaneous category including mental disorders and cerebral palsy. Inflammation occurs quite often since there is so little room in the wrist and hand for all the required tendons, ligaments, and muscles. The pain, swelling and stiffness almost always gets worse when the musician plays. Precipitating factors include lack of proper conditioning, overzealous practice, preexisting trauma, specific technical problems, instrument problems, repertoire, and changing teachers.

In diagnosing inflammatory conditions, as well as other problems, the physician must take a careful history and rule out systemic diseases such as arthritis. Many times physical therapists can do a better examination of the hand. It is essential to watch the patient play and reexamine him or her afterward. The most conservative treatments should be tried first, although surgery and other radical therapies do have a place in treatment of musicians. It is difficult to get musicians to stop playing until the pain is gone, but they must understand that playing should not hurt. Whether inflammatory problems eventually lead to motor control problems is unknown.

Dr. Newmark said many of these patients had been to numerous health professionals and tried all kinds of traditional and alternative therapies. Due to the publicity surrounding such cases as Leon Fleisher and Gary Graffman, Massachusetts General has seen a marked increase in musician patients. However, other cities such as Denver, San Francisco, and Rochester also have fine clinics.

Biofeedback

William LeVine MD, of the University of Kansas School of Medicine, summarized his experience in using biofeedback with violin and viola players. Most of his patients have presented with excessive tension in the left thumb. This tension spreads throughout the hand and sometimes into the arm and shoulder, causing numerous problems. Electrodes were placed on the abductor pollicis muscle, used in squeezing the thumb and forefinger together, and connected to a biofeedback machine. When a predetermined threshold of muscular contraction was exceeded, an auditory or visual signal alerted the player that he/she was using too much tension. The player began with simple scales and worked up to performance pieces, trying to play without setting off the signal. As training went on, the threshold was lowered. Dr. LeVine has found it best to train the player to use the machine and leave him/her alone to experiment. Results are remarkably fast, sometimes occurring in as little as five minutes.

Dr. LeVine also showed a videotape of his work with a violist bothered by muscle spasms. In this case, temperature biofeedback was used to try to control the hand and arm spasms. The performer was told not to play until the temperature of her hands reached a certain point and to stop as soon as it was lower than the threshold. This type of biofeedback training is more difficult and takes much longer. However, this performer was able to master it and has her problem under control.

In an afternoon workshop Dr. LeVine set up his biofeedback machinery and invited violinists to experiment with the technique. Several violinists tried out the system and almost immediately were able to determine certain times when left hand tension increased and made progress in decreasing that tension. One also experimented with excessive squeezing by the neck. This proved a little more difficult to adjust, but some progress was made. A trombonist asked if the technique might lend itself to elimination of excessive left biceps tension when playing high notes. Though Dr. LeVine had not considered this application before, electrodes were attached to the trombonist's biceps area while he tried playing a difficult section of Ravel's "Bolero." Adjustment of the threshold level allowed him to get a feeling for how much tension was actually necessary to produce the notes and how much might be considered excessive.

Dr. LeVine postulated that some type of pressure biofeedback device would be even more valuable to

musicians. Most hospitals or universities with medicine, psychology, or physical therapy programs probably have standard biofeedback machinery, so access to this type of training opportunity is not as limited as musicians may assume.

Pianists' Problems

Upper extremity problems of pianists were discussed from a musician's point of view by Edna Golandsky, cofounder of the Dorothy Taubman Institute of Piano in Amherst, Massachusetts. Ms. Taubman is well known as a champion of the scientific approach to piano pedagogy seeking to avoid pain and injuries. Much of current piano technique is built on faulty alignment of the fingers, hand, and arm. The much-prized rounded fingers become restricted and tense, leading to damage of the long extensor muscles. Since the fingers can stretch only so far, finger isolation exercises can often lead to more problems instead of strength. Fast-fingering exercises can cause spasms because they interrupt momentum. Legato motion is often impossible to achieve without using the pedal. Too much relaxation of the hand transfers tension to the shoulders and back. Endurance training masks the symptoms of fatigue and leads to further injury. In general, constant extremes of any sort of motion can be very harmful. Far too many pianists accept pain and fatigue, when movements should feel good.

Ms. Taubman emphasized coordinate movements with a delicate balance of relaxing and contracting muscles. The performer should concentrate on dropping fingers rather than raising them, balancing the arm on the fingers, using the arm for horizontal motions, and using the weight of the arm to give power. Faulty technique caused by the current confused state of piano pedagogy can lead to performance anxiety and memory lapses as well as physical injury. Ms. Taubman firmly believes that reeducation of movement can relieve a great number of hand disorders. She strongly disagreed with radical treatments such as surgery. Many operative failures have been reported, including the much-publicized return of Leon Fleisher, and the effects of surgery on musical movements are largely unknown. Squeezing a ball, stretching and pulling exercises, and splinting can also be destructive.

Wind Players' Problems

Joseph Robinson, principal oboe with the New York Philharmonic, spoke on problems unique to wind instrument players, particularly oboists. Unlike other wind players, oboists always have a surplus of air and a very small outlet for it. The result is a very high degree of internal compression. Oboists, as well as other wind players, usually choke off air with the throat to create a pianissimo, rather than breathing more softly, and often take in more air while holding air back at the same time. Since control of breathing is the most important issue for a wind player other than fingering, effective breathing techniques are critical. Ironically, instrumentalists have the most control over the wind when there is the least air available. Teachers who have studied breathing almost all agree that breathing down and in, up and out is the best method. This is similar to a controlled Heimlich maneuver. For the oboist, the crucial part is remembering to exhale, to avoid what feels like an impending explosion.

Vocal Performance

Another session focused on the professional voice. Minoru Harano MD, of Kurame University in Japan, discussed control mechanisms used in vocal performance. The intrinsic and extrinsic laryngeal muscles control the vocal fold tissues. Electromyographic recordings comparing professional and nonprofessional singers clearly show how these muscles produce specific vocal sounds. Ingo Titze PhD, University of Iowa, summarized the biomechanics of the larynx. This is the only organ of the body where tissues collide at rapid rates for prolonged periods of time. Because of this and muscle fatigue, the larynx is susceptible to rapid deterioration. Lorraine Ramig PhD, a speech pathologist from the University of Colorado, profiled the voice as a key to neurological disorders. Preliminary research has shown that vocal analysis of patients with various neurological diseases can provide important clinical information. Oren Brown, of Juilliard, discussed techniques for training and remediating the voice. The presentation included factors involved in normal phonation and procedures for correction of various malfunctions. A panel of physicians, speech pathologists, voice teachers, and scientists then discussed medical care of vocalists.

Music and Medicine

Another panel concerned itself with music and medicine in general. Otolaryngologist Bruce Jafek MD, University of Colorado School of Medicine, has treated many vocalists and other professionals who use their voices a great deal. He stressed that communication and education are critical, that expectations must be clearly understood on both sides. Singing makes major demands on the larynx and the services of a speech therapist are often essential. Dr. Jafek recommended a team approach to all vocal disorders.

Peter Ostwald MD, a psychiatrist, has begun a spe-

cialized clinic for musicians at San Francisco Medical Center. The patients seen by this clinic fall into distinct groups with different problems requiring different treatment. These groups are students, professional orchestral musicians, composers, and VIPs. Their problems require physicians familiar with music so they will be readily accepted. Ostwald considered it important to see the musician actually play. He agreed with the team approach, stressing the availability of mental health professionals. The complaints of musicians are very real, and it often requires a great deal of courage for the individual to come forward. Regardless of the problem, it will involve mental anguish and the need for emotional support. Dr. Ostwald and his associates are beginning to build a network of physician referrals.

Rudolf Pyka MD, of California, spoke about orthopedic problems. In general, amateurs fatigue before experts, and functional changes come before anatomical ones. The movements involved are often so small that the musician's description is generally more useful than any measurements science can presently make. The correct diagnosis is critically important. Most therapies are designed for the average person, not high-performance musicians. Dr. Pyka agreed with other speakers that retraining often can solve the problem and that surgery should be used only as a last resort. Hand surgery does not always afford predictable results, and musical results are almost entirely unknown. An open, honest discussion of the diagnosis and available therapies so the patient can make an informed choice is the physician's most important service.

Stuart Schneck MD, a neurologist, has begun an upper extremity clinic at the University of Colorado Medical Center modeled after that at Massachusetts General. The cases he sees most are occupational cramps and other motor control problems. Many of these patients have tried more practice, changing techniques, or changing repertoire to no avail. They often engage in a great deal of self-treatment until the problem reaches the critical stage. They are terrified to let anyone know of their problem and finally come to the physician with anxiety and depression piled on top of their physical problems. Many teachers are not aware of anatomical and physiological principles, so they are unable to advise their students properly. Physicians, on the other hand, cannot devote themselves entirely to music medicine because there are relatively few patients. Both music teachers and physicians must become more aware of each other's fields and work together. Unfortunately, many musicians are too ready to undergo surgery as a quick fix. Physicians need to become aware of nontraditional methods of care, such as the various movement education techniques. Dr. Schneck made a plea for organized music to recognize and accept the occupational problems occuring in their field.

Wilbur Gould MD, is director of the Recording and Research Center of the Denver Center for the Performing Arts. This center, the first of its kind in the nation, uses advanced audio and video recording techniques to study the function of the human voice. Topics of research include vocal problems, the relationship between psychological and physiological difficulties in stage fright, the effect of environmental factors on vocal performance, and achievement of maximum voice quality. For use at the center, Dr. Gould developed GLIMPES, a glottal imaging program. He is also one of the founders of the Symposia on the Care of the Professional Voice, usually held at Juilliard. Dr. Gould emphasized that vocal problems are very complex and require a team approach. Physicians must understand the problems of musicians, more so than music itself, and work closely with voice teachers. Research into the effects of various medications on the larynx is badly needed.

Physician-Musician Cooperation

Though panelists may have disagreed on specifics, they all hoped for more cooperation between physicians and musicians. Musicians must understand that medicine still contains many gray areas and is often more art than science. They should be patient because a quick fix is usually not the best answer. Sometimes there are very difficult choices for both patient and doctor.

At the conclusion of the conference, a panel discussion focused on what research needs to be done and where the present conference might lead. The audience was asked for their input. Many musicians wanted research that would help them be more effective teachers. Others wanted proof that music is really beneficial in some quantitative way. Scientists expressed interest in music perception as a function of experience, computer models of performance, and the relationship between function, health, and pedagogy. Several panelists reminded the musicians present that they can do a lot of their own research; physicians and other scientists do not necessarily have all the answers. At the very least, they will need intelligent cooperation from musicians and teachers to carry out their proposals and to make sure they are moving in practical directions.

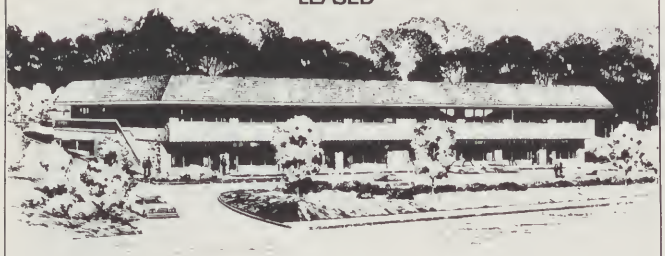
A number of the presenters and audience had the feeling of being on the threshold of a brand new field. How do we clarify and organize such a field? How do we insure the continuity of basic and applied research? Should we defer any research until our overall goals are clearly established and agreed upon, or should we begin

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many small projects and allow larger goals to evolve?

The excitement of the moment did not lead to real answers, but many suggestions were offered. A European presenter said a newsletter would be valuable to him. A conservatory dean thought there might be interest in a professional association. The Music Teachers National Association offered to publish a list of physicians dealing with music medicine in their publication, *American Music Teacher*, if this would be helpful. Almost everyone agreed that more conferences, perhaps biannually, should be held. The entire conference was videotaped, and these tapes will be made available to those interested. The University of Colorado Press plans to publish the proceedings.

SUSAN E. HARMAN
Reference and Circulation Librarian.

Selected Medical Literature Searches

The following are among the computerized medical literature searches provided to Med-Chi members during November 1984.

		No. of Citations
1.	Apraxia in childhood	23
2.	Cystinuria	46
3.	Differential diagnosis and treatment of spermatic cord torsion and epididymitis	40
4.	Health facility closure	96
5.	Mental and cognitive disorders in multiple sclerosis	41
6.	Neuroleptic malignant syndrome	34
7.	Pedophilia	18
8.	Potter's syndrome	12
9.	Prostatic neoplasms metastasizing to the brain	14
10.	Satellite hospitals	41

If you would like a copy of one of these searches or a search run on any biomedical topic, call or write the library.

SUSAN E. HARMAN
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FEBRUARY 1985

UPDATE ON HTLV-III TESTING

TESTING FOR HTLV-III VIRUS

Enzyme Linked Immunosorbent Assay (ELISA) has been developed as a screening test for antibody to human T-cell lymphotropic virus type III (HTLV-III), a pathogenic retrovirus. If the antibody testing is positive by ELISA, the most accepted method to confirm the presence of HTLV-III antibody at this time is the Western blot technique. The Centers for Disease Control (CDC) believes these tests to be reliable even though false positive and false negative results have been reported in the literature. Culture kits for HTLV-III virus will not be available in the near future.

Initially, only blood banks will be performing these tests. Blood donors that test HTLV-III antibody positive will be informed with a recommendation to contact their private physician for guidance and follow-up.

There is concern that some individuals at risk for HTLV-III infection may donate blood to learn their antibody status. In order to avoid this, the Maryland State AIDS Task Force has recommended that alternative facilities be identified for HTLV-III antibody testing.

WHO SHOULD BE TESTED?

The AIDS Task Force recommends HTLV-III testing for the following groups of people:

1. Blood donors;
2. Participants in research on HTLV-III infection;
3. Patients displaying symptoms of HTLV-III infection;
4. Patients who believe they are at high risk of HTLV-III exposure but only after a frank discussion of the implications of testing for HTLV-III antibody.

CONCERNS ABOUT HTLV-III TESTING

The National Gay Task Force has raised several concerns which include the following:

1. The implications of false positive and false negative test results;
2. The fact that test results become part of a permanent medical record which could be the basis for denying health or life insurance, and the potential for job discrimination;
3. Psychological pressures of knowing one has tested positive to antibodies.

Statements Regarding the Meaning of a Positive HTLV-III Antibody Test

1. Screening tests which indicate the presence of antibody to HTLV-III should be repeated with a confirmatory test (e.g., Western blot test).

2. Persons with confirmed positive HTLV-III antibody tests are presumed to have been exposed to and infected with HTLV-III. These persons may have symptoms related to the infection, or they may be completely asymptomatic.

3. Exactly how long HTLV-III persists in persons with antibody to the virus is not known. There is information which suggests that the virus may be carried over a period of years, despite the development of antibodies. Future results of prospective studies will be better able to determine the length of viral carriage.

4. Some people infected with HTLV-III will develop the acquired immunodeficiency syndrome (AIDS); others may develop AIDS-related complex (ARC) (lymphadenopathy, oral candidiasis, chronic diarrhea, fever, unexplained weight loss, etc); some may develop transient "glandular fever" with rash; while others may remain completely asymptomatic. In some studies, 5% to 19% of seropositive men developed AIDS within 2-5 years after a previously collected serum sample was tested and found to be seropositive. An additional 25% developed generalized lymphadenopathy, oral candidiasis, or other ARC within the same interval. The long-term prognosis for most persons infected with HTLV-III is unknown.

5. People with AIDS or ARC and infected asymptomatic individuals may transmit HTLV-III to others. Until viral cultures for HTLV-III become routinely available, the blood, saliva, and semen of a person who has HTLV-III antibody should be presumed to be infectious. The virus may be transmitted through sexual intimacy, intimate kissing, sharing needles, receipt of blood or blood products, and from an infected mother to her infant. Casual contact, such as non-intimate physical contact, sharing meals, sneezing or coughing, has not been shown to transmit the virus.

Recommendations to Physicians To Whom HTLV-III Seropositive Patients are Referred

When a patient is referred to a physician because of HTLV-III seropositivity, the physician should:

1. Determine whether the person has had a confirmatory test (currently the Western blot) for HTLV-III antibody. If not confirmed, obtain additional blood for a confirmatory test.

2. Obtain a medical history which includes information relative to the patient's sexual and drug use history since male-to-male sexual contact and shared needles among drug abusers are the two most frequent modes of transmission. Other risk factors may include receipt of blood or blood products, sexual contact with an individual who has or is at high risk for AIDS (e.g. heterosexual drug abusers or female prostitutes) and recent immigration from Haiti. Relevant symptoms include: fever, night sweats, unexplained weight loss, oral thrush, lymphadenopathy, persistent diarrhea, cough and shortness of breath.

3. Perform a physical examination with particular attention to lymph node enlargement, oral candidiasis, and skin or mucosal lesions that may be indicative of Kaposi's sarcoma.

4. Perform tests to evaluate the patient's immune system. Initial tests should include a CBC with differential for leukopenia and lymphopenia, and skin tests for anergy, including PPD, mumps, candida, and trichophyton skin test antigens. An additional test may include T-lymphocyte studies (T-helper/T-suppressor cell ratio). Screening tests for sexually transmitted diseases such as syphilis, gonorrhea, hepatitis B and enteric parasites should be considered. Other tests may be indicated depending on the patient's symptoms and signs.

5. Refer the patient for biopsy if any suspicious skin or mucosal lesions are noted. Consider lymph node biopsy in selected cases.

6. Inform the patient of the significance of positive test results, recommend appropriate means to interrupt possible transmission of HTLV-III, reinforce the importance of periodic follow-up and refer patient to community resources for support (e.g. HERO, The Health Education Resource Organization, 301-947-2437).

7. Report all confirmed AIDS cases to the local Health Department. ARC cases are reportable in Baltimore City only.

8. Conduct periodic health assessments.

Recommendations Regarding Persons with Acquired Immunodeficiency Syndrome (AIDS), AIDS-Related Complex (ARC) or a Confirmed Positve HTLV-III Antibody Test

I. General

A. Regular medical evaluation and follow-up of infected* persons are advised, especially for individuals who develop signs or symptoms suggestive of progressive HTLV-III infection (i.e., fevers, unexplained weight loss, swollen lymph glands, persistent cough or diarrhea). While there is no current treatment for HTLV-III retroviral infection, early treatment of AIDS-related infections will improve the quality of life and may extend the survival of AIDS patients.

*In this document, "infected" people are defined as AIDS cases, persons with ARC and persons with confirmed positive HTLV-III antibody tests. They should be presumed to be infectious until viral cultures are readily available.

B. Under no circumstances, should blood, plasma, body organs, sperm, or other tissues from infected persons be donated for use by other persons.

C. Toothbruses, razors, or other implements that could become contaminated with blood should not be shared.

D. Surfaces and items contaminated with blood, secretions or excretions from infected persons should be cleaned with a solution made from one part of household bleach (5.25% sodium hypochlorite) freshly diluted with nine parts of water.

E. While transmission via saliva may be unlikely, activities which transfer saliva, such as intimate kissing, oral-genital contact, or biting, should be avoided. Separate utensils or disposable dishes for infected individuals are not required if the utensils and dishes are thoroughly washed with hot water and soap. It is good general health practice not to share drinking or eating utensils in order to avoid transmission of viral and bacterial diseases.

F. Active participation in training sessions for cardiopulmonary resuscitation (hands-on training with manikins) should not be undertaken by infected individuals.

G. Infected individuals should not share needles.

Sexual Activity

A. Non-infected people may acquire infection through sexual activity with an infected individual. At this time, it is not known if there is additional health risk involved in sexual activity between two infected individuals. The steady sexual contact(s) of an infected person may wish to have his/her antibody status determined.

B. Infected individuals should refrain from all sexual activity which results in transfer of semen or other body fluids to a person who is not infected with HTLV-III. The efficacy of condoms in preventing infection with HTLV-III is unproven, but the consistent use of them may reduce transmission.

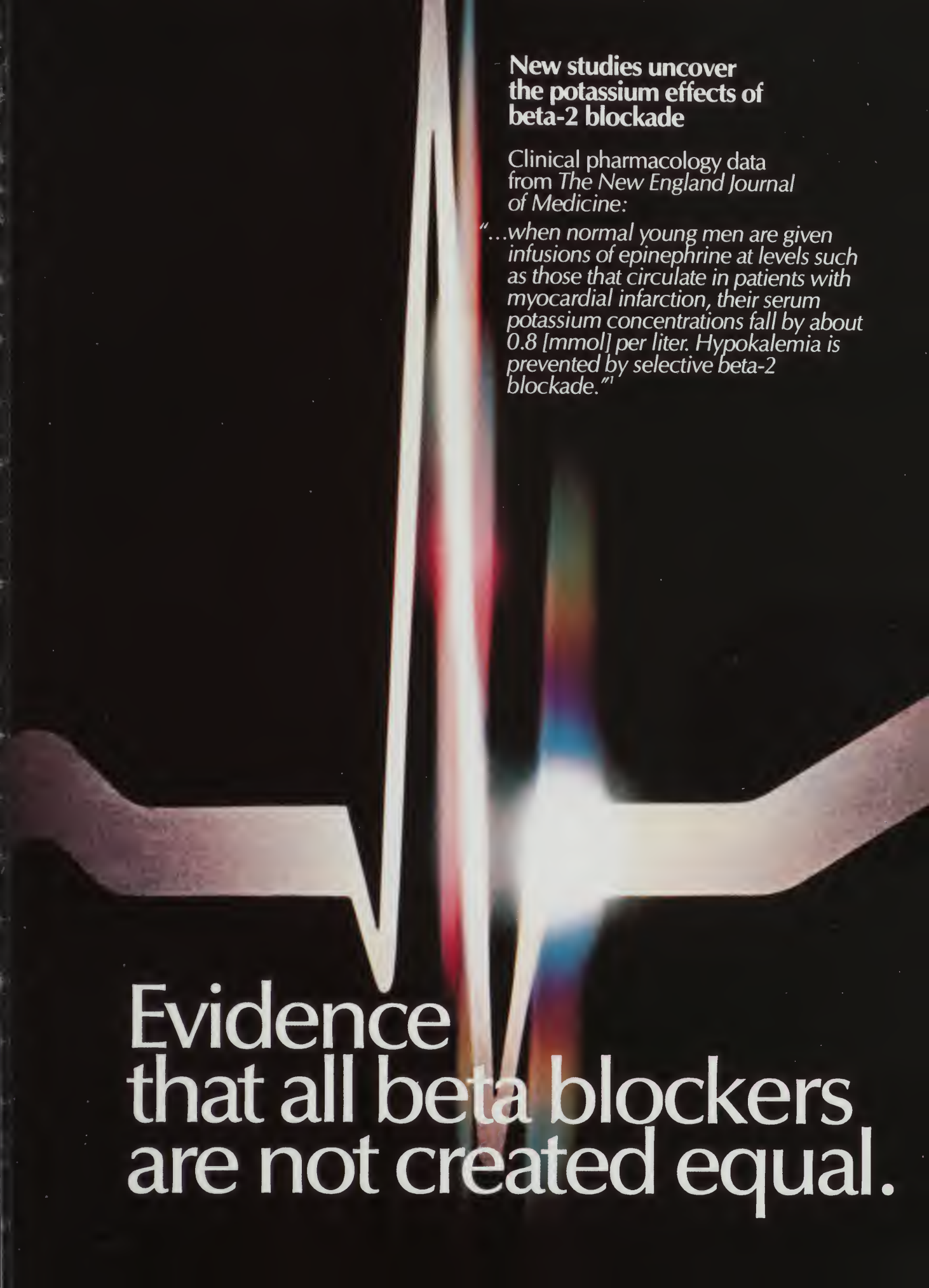
C. Infected persons should be considerate of potential sexual partners and inform them of their positive HTLV-III antibody status.

D. If infected women become pregnant, their infants are at increased risk of developing HTLV-III infection. Women who have antibody to HTLV-III or who are sexual partners of infected men should adopt effective birth control measures.

SOURCE

Guidelines were prepared by CDC, Atlanta, Georgia, adapted and expanded by the Baltimore City Health Department and agreed to by the Maryland State AIDS Task Force of the Maryland Department of Health and Mental Hygiene.

CONTINUED NEXT MONTH



New studies uncover the potassium effects of beta-2 blockade

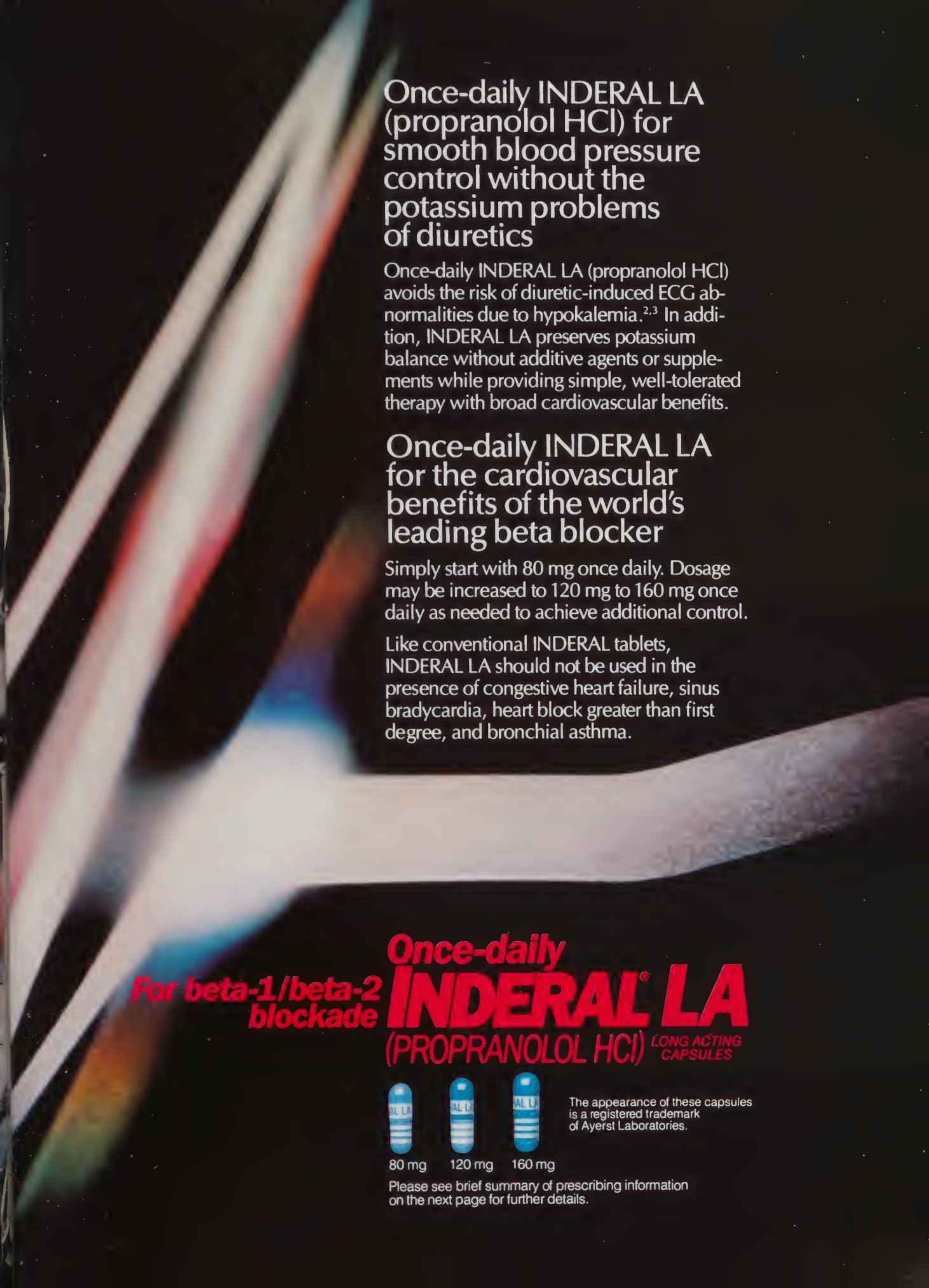
Clinical pharmacology data from *The New England Journal of Medicine:*

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INDERAL LA Capsules (80, 120, and 160 mg) release propranolol HCl at a controlled and predictable rate. Peak blood levels following dosing with INDERAL LA occur at about 6 hours and the apparent plasma half-life is about 10 hours. When measured at steady state over a 24-hour period the areas under the propranolol plasma concentration-time curve (AUCs) for the capsules are approximately 60% to 65% of the AUCs for a comparable divided daily dose of INDERAL tablets. The lower AUCs for the capsules are due to greater hepatic metabolism of propranolol, resulting from the slower rate of absorption of propranolol. Over a twenty-four (24) hour period, blood levels are fairly constant for about twelve (12) hours then decline exponentially.

INDERAL LA should not be considered a simple mg for mg substitute for conventional propranolol and the blood levels achieved do not match (are lower than) those of two to four times daily dosing with the same dose. When changing to INDERAL LA from conventional propranolol, a possible need for retitration upwards should be considered especially to maintain effectiveness at the end of the dosing interval. In most clinical settings, however, such as hypertension or angina where there is little correlation between plasma levels and clinical effect, INDERAL LA has been therapeutically equivalent to the same mg dose of conventional INDERAL as assessed by 24-hour effects on blood pressure and on 24-hour exercise responses of heart rate, systolic pressure and rate pressure product. INDERAL LA can provide effective beta blockade for a 24-hour period.

The mechanism of the antihypertensive effect of INDERAL has not been established. Among the factors that may be involved in contributing to the antihypertensive action are (1) decreased cardiac output, (2) inhibition of renin release by the kidneys, and (3) diminution of tonic sympathetic nerve outflow from vasomotor centers in the brain. Although total peripheral resistance may increase initially, it readjusts to or below the pretreatment level with chronic use. Effects on plasma volume appear to be minor and somewhat variable. INDERAL has been shown to cause a small increase in serum potassium concentration when used in the treatment of hypertensive patients.

In angina pectoris, propranolol generally reduces the oxygen requirement of the heart at any given level of effort by blocking the catecholamine-induced increases in the heart rate, systolic blood pressure, and the velocity and extent of myocardial contraction. Propranolol may increase oxygen requirements by increasing left ventricular fiber length, end diastolic pressure and systolic ejection period. The net physiologic effect of beta-adrenergic blockade is usually advantageous and is manifested during exercise by delayed onset of pain and increased work capacity.

In dosages greater than required for beta blockade, INDERAL also exerts a quinidine-like or anesthetic-like membrane action which affects the cardiac action potential. The significance of the membrane action in the treatment of arrhythmias is uncertain.

The mechanism of the antimigraine effect of propranolol has not been established. Beta-adrenergic receptors have been demonstrated in the pial vessels of the brain.

Beta receptor blockade can be useful in conditions in which, because of pathologic or functional changes, sympathetic activity is detrimental to the patient. But there are also situations in which sympathetic stimulation is vital. For example, in patients with severely damaged hearts, adequate ventricular function is maintained by virtue of sympathetic drive which should be preserved. In the presence of AV block, greater than first degree, beta blockade may prevent the necessary facilitating effect of sympathetic activity on conduction. Beta blockade results in bronchial constriction by interfering with adrenergic bronchodilator activity which should be preserved in patients subject to bronchospasm.

Propranolol is not significantly dialyzable.

INDICATIONS AND USAGE. Hypertension: INDERAL LA is indicated in the management of hypertension; it may be used alone or used in combination with other antihypertensive agents, particularly a thiazide diuretic. INDERAL LA is not indicated in the management of hypertensive emergencies.

Angina Pectoris Due to Coronary Atherosclerosis: INDERAL LA is indicated for the long-term management of patients with angina pectoris.

Migraine: INDERAL LA is indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established and propranolol is not indicated for such use.

Hypertrophic Subaortic Stenosis: INDERAL LA is useful in the management of hypertrophic subaortic stenosis, especially for treatment of exertional or other stress-induced angina, palpitations, and syncope. INDERAL LA also improves exercise performance. The effectiveness of propranolol hydrochloride in this disease appears to be due to a reduction of the elevated outflow pressure gradient which is exacerbated by beta-receptor stimulation. Clinical improvement may be temporary.

CONTRAINDICATIONS. INDERAL is contraindicated in 1) cardiogenic shock; 2) sinus bradycardia and greater than first degree block; 3) bronchial asthma; 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with INDERAL.

WARNINGS. CARDIAC FAILURE: Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or INDERAL should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of INDERAL therapy. Therefore, when discontinuance of INDERAL is planned the dosage should be gradually reduced over at least a few weeks, and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If INDERAL therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute INDERAL therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema)— PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. INDERAL should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY: The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

INDERAL (propranolol HCl), like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, e.g., dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOGLYCEMIA: Beta-adrenergic blockade may prevent the appearance of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more difficult to adjust the dosage of insulin.

THYROTOXICOSIS: Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol does not distort thyroid function tests.

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS. *General:* Propranolol should be used with caution in patients with impaired hepatic or renal function. INDERAL (propranolol HCl) is not indicated for the treatment of hypertensive emergencies.

Beta adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should be told that INDERAL may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

Clinical Laboratory Tests: Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS: Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if INDERAL is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

Pregnancy: Pregnancy Category C. INDERAL has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose.

There are no adequate and well-controlled studies in pregnant women. INDERAL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: INDERAL is excreted in human milk. Caution should be exercised when INDERAL is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS. Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: bradycardia; congestive heart failure, intensification of AV block; hypotension; paresthesia of hands; thrombocytopenic purpura; arterial insufficiency, usually of the Raynaud type.

Central Nervous System: lightheadedness; mental depression manifested by insomnia, lassitude, weakness, fatigue; reversible mental depression progressing to catatonia, visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Gastrointestinal: nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory: bronchospasm.

Hematologic: agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-Immune: In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: alopecia, LE-like reactions, psoriasiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

DOSAGE AND ADMINISTRATION. INDERAL LA provides propranolol hydrochloride in a sustained-release capsule for administration once daily. If patients are switched from INDERAL tablets to INDERAL LA capsules, care should be taken to assure that the desired therapeutic effect is maintained. INDERAL LA should not be considered a simple mg for mg substitute for INDERAL. INDERAL LA has different kinetics and produces lower blood levels. Retitration may be necessary especially to maintain effectiveness at the end of the 24-hour dosing interval.

HYPERTENSION—*Dosage must be individualized.* The usual initial dosage is 80 mg INDERAL LA once daily, whether used alone or added to a diuretic. The dosage may be increased to 120 mg once daily or higher until adequate blood pressure control is achieved. The usual maintenance dosage is 120 to 160 mg once daily. In some instances a dosage of 640 mg may be required. The time needed for full hypertensive response to a given dosage is variable and may range from a few days to several weeks.

ANGINA PECTORIS—*Dosage must be individualized.* Starting with 80 mg INDERAL LA once daily, dosage should be gradually increased at three to seven day intervals until optimum response is obtained. Although individual patients may respond at any dosage level, the average optimum dosage appears to be 160 mg once daily. In angina pectoris, the value and safety of dosage exceeding 320 mg per day have not been established.

If treatment is to be discontinued, reduce dosage gradually over a period of a few weeks (see WARNINGS).

MIGRAINE—*Dosage must be individualized.* The initial oral dose is 80 mg INDERAL LA once daily. The usual effective dose range is 160-240 mg once daily. The dosage may be increased gradually to achieve optimum migraine prophylaxis. If a satisfactory response is not obtained within four to six weeks after reaching the maximum dose, INDERAL LA therapy should be discontinued. It may be advisable to withdraw the drug gradually over a period of several weeks.

HYPERTROPHIC SUBAORTIC STENOSIS—80-160 mg INDERAL LA once daily.

PEDIATRIC DOSAGE—At this time the data on the use of the drug in this age group are too limited to permit adequate directions for use.

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HBP Commentary

Effects of Antihypertensive Agents on Lipids, Lipoproteins, and Coronary Heart Disease

ROGER SHERWIN MB, BChir and CAROL LEWIS MPH, ScD

Dr. Sherwin is Professor, Department of Epidemiology and Preventive Medicine, University of Maryland School of Medicine, Baltimore, and Dr. Lewis is Executive Director, Maryland High Blood Pressure Commission.

It is possible the reduction of blood pressure may reduce the risk of coronary heart disease (CHD) but other effects of antihypertensive agents, especially on blood lipids and lipoproteins, may enhance the risk of CHD. Major randomized clinical trials of drug treatment for hypertension have shown reductions in stroke but no consistent reduction of CHD. The elevation of low-density lipoprotein (LDL) cholesterol by some diuretics and the depression of high-density lipoprotein (HDL) cholesterol by several beta-blocking agents are both potentially serious effects of antihypertensive drug therapy. These findings increase the complexities of decisions that have to be made as to how and when to initiate drug treatment of hypertension and may have important implications for its management.

The effects of antihypertensive agents have been reviewed recently by Sherwin and Cutler.[1] They pointed out that the benefits obtained from treatment in the major clinical trials of hypertension have been selective. There are many more deaths from coronary heart disease (CHD) than from cardiovascular disease (CVD), namely stroke, among hypertensives.

Table 1 depicts the total deaths in seven clinical trials of the drug treatment of hypertension. In the control groups, deaths from CHD occurred almost four times as frequently as deaths from CVD.[2–9] However, there were only small reductions in CHD between experimental and control groups in these trials, but large differences between these groups for CVD. More stroke deaths than CHD deaths were prevented.

Potential Adverse Effects of Antihypertensive Treatments

While the reduction of blood pressure *per se* may reduce the risk of CHD, some of the antihypertensive agents may be enhancing the risk of CHD in other ways and hence neutralizing the benefit of reduced blood pressure. This possibility is receiving increasing attention. For example, the possible adverse effect of a vigorous program of treatment for high blood pressure in the Multiple Risk Factor Intervention Trial (MRFIT) has been discussed in this *Journal*.[10] The effects of diuretics in elevating serum glucose and uric acid and in lowering serum potassium were well known before the Hypertension Detection and Follow-up Program (HDFP) and MRFIT studies. However, not until these trials were in progress were the effects of antihypertensive agents on the serum lipids and lipoproteins generally recognized. The major effects of the more commonly used diuretics and of the beta-adrenergic blocking agents on total cholesterol, triglycerides, very low-density lipoprotein (VLDL) cholesterol, high-density lipoprotein (HDL) cholesterol, and low-density lipoprotein (LDL) cholesterol are shown in Table 2.

Hydrochlorothiazide and the thiazide derivative, chlorthalidone, have essentially similar effects. A modest elevation in total cholesterol is accompanied by a much more marked increase in triglycerides and the closely correlated VLDL cholesterol; the LDL choles-

Table 1. Impact of Drug Treatment for Hypertension on the Incidence of Coronary Heart Disease (CHD) and Cerebrovascular Disease (CVD)

	CHD Deaths		CVD Deaths	
	Experimental	Control	Experimental	Control
The Veteran's Administration Co-operative Study I	0	1	0	0
The Veteran's Administration Co-operative Study II	6	11	1	7
Hypertension Detection and Follow-Up Program	131	148	29	52
The United States Public Health Service Hospitals Cooperative Study	1	1	0	0
The Australian Therapeutic Trial in Mild Hypertension	5	11	3	6
The Oslo Study	6	2	0	2
The Multiple Risk Factor Intervention Trial (hypertensives)	80	79	*	*
TOTALS	229	253	33	67

* Data not yet available

HBP Commentary is contributed by the Maryland High Blood Pressure Commission. Editors: R. Patterson Russell MD, Past Chairman; Donald O. Fedder PharmBS, DrPH, Chairman; and Carol Lewis MPH, ScD, Executive Director.

Table 2. Effects of Certain Diuretic and Beta-Adrenergic Blocking Agents on Lipids and Lipoproteins

	Total Cholesterol	Triglycerides (and VLDL Cholesterol)	HDL Cholesterol	LDL Cholesterol
Hydrochlorothiazide	↑	↑↑	?	↑
Chlorthalidone	↑	↑↑	?	↑
Propranolol	?	↑↑↑	↓↓	?
Metroprolol	?	↑↑	↓	?
Atenolol	?	↑↑	↓	?
Pindolol	?	?	?	?

terol is increased in about the same proportion as the total cholesterol, and there is no consistently observed effect on HDL cholesterol.

The beta-adrenergic blocking agents have less immediately obvious effects because there is no consistent effect on the most frequently monitored lipid, total cholesterol. However, there is a major effect on triglycerides and VLDL cholesterol, especially with the most widely used agent, propranolol, which has an even more marked effect on triglycerides than do the diuretics. Whereas LDL cholesterol is not usually elevated with the beta blockers, HDL cholesterol is lowered by most beta blockers, especially by propranolol.

Long-term Risk with Antihypertensive Agents

It is probably true to say that increases in LDL cholesterol and concomitant increases in total cholesterol are potentially atherogenic and therefore undesirable in the long term. With respect to triglycerides and the closely related VLDL cholesterol, the most thorough review of the available data concluded that these lipids are not independent risk factors for CHD.[11] HDL cholesterol, however has a strong, independent, and inverse relationship with the risk of CHD.[12] Reductions in HDL cholesterol should be a source of greater concern than elevations of triglycerides and VLDL cholesterol. Thus the beta blockers, especially propranolol, would carry greater long-term risks than the diuretics, because of the reduction in HDL cholesterol observed with most of the beta blockers.

Even small adverse effects on lipids and lipoproteins are of major concern in the management of hypertension, especially when treatment begins in young adult life and may be continued for five or six decades. There also is strong evidence of synergism between lipid abnormalities and hypertension as risk factors for CHD.

Implications for Hypertension Management

These findings are important for the management of high blood pressure. They serve to remind us that *useful pharmacologic effects are rarely available without some risk of potentially adverse effects.* In any given clinical circumstances, *the likelihood of benefit of treatment should outweigh the risk of harm.* Unfortunately, neither the benefits nor the risks may be exhibited in the short term. The benefits of treating hypertension may not be fully apparent for many years; neither may the possible negative effects on atherosclerosis resulting from lipid changes. Even clinical trials lasting five years may not adequately assess the overall net effects of the treatment of hypertension. There is currently vigorous debate concerning both the level of blood pressure at which pharmacologic treatment should be initiated and the sequence in which the several classes of antihypertensive agents should be used. The effects of diuretics and beta blockers on lipids make these questions even more complex. This emphasizes the importance of the prevention of hypertension by the maintenance of normal body weight and moderation in the dietary intake of salt, and the initial treatment of mild hypertension by appropriate dietary changes rather than by pharmacologic treatment.

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The system of administering insulin to the diabetic through a mechanical device strapped to the side of the patient that pushes insulin at a slow rate into the abdominal wall through a tubing and needle device is called an "open-loop pump." This type of pump may be operated by the patient (pen pump) or by a battery propelled system.

Persons suited for a trial of management of their diabetes by the "pump" method should include the following:

1. Those willing to do blood glucose self-monitoring as many as four to six times daily.
2. Those willing to follow a well-controlled meal plan.
3. Those willing to adjust their "life-style" to having a mechanical device attached to their bodies continuously day and night.
4. Those having the ability to recognize a hypoglycemic reaction through a well-functioning autonomic nervous system.
5. Those who can adjust psychologically to the trials and tribulations of diabetic exigencies.
6. Those who can afford approximately $2,000 per year for the purchase and maintenance of the pump system.

About one-third of the patients placed on insulin pumps have discontinued the use of the devices because of inconvenience, recurrent infections at needle sites, expense, or recurrent hypoglycemic reactions.

At this time, the "open-loop pump system" of administering insulin is an experimental program. Some patients will be able to adapt to this program, but it is not suitable for the majority of the insulin-dependent diabetic population.

Many diabetologists are of the opinion that equally good control of diabetes can be obtained at less expense and inconvenience by means of multiple injections of insulin daily.

DeWITT E. DeLAWTER MD
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Osteoarthritis V: Medical Management

THOMAS M. ZIZIC MD

Dr. Zizic is Associate Professor of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD.

Osteoarthritis has one of the highest morbidity rates of all the diseases that affect humans. In the United States there are an estimated 180,000 bed or wheelchair invalids due to osteoarthritis, but there is an extensive morbidity rate that is often unidentified and regarded as an insoluble medical problem.[1] Although the current treatment of osteoarthritis is symptomatic and nonspecific, in most patients a great deal can be done to relieve discomfort and, in some cases, prevent or retard disease progression. Rational therapy requires a thorough understanding of the clinical manifestations and pathophysiology that have been covered in previous issues of this series. Only those aspects particularly germane to the medical management of these patients will be recapitulated in this article.

Clinical Manifestations

The major symptom of osteoarthritis is a deep, aching pain in the joints. Initially this is generally present only with motion or weight bearing, but subsequently it may progress to pain even at rest. Although some patients may have morning stiffness, it is generally transient and only rarely lasts longer than a few minutes. Stiffness is common after prolonged inactivity but may be apparent even after a short rest. In subacute stages there may be considerable tenderness and slight warmth of the affected joints, but generally, capsular swelling, intermittent synovial effusion, decreased range of joint motion, and barely detectable joint deformity are the only objective findings.

Pathophysiology

Although the prevalence of osteoarthritis does increase with age, the disease is not due to simply chronological age and wear and tear. There are many differences between the joints of the simply aged and osteoarthritic joints.[2,3] In chronologically aged joints, fibrillation does occur, but it is always on the nonload-bearing surfaces of the cartilage, and it does not advance to form clefts.[4] Virtually all periarticular and intraarticular tissues markedly increase in volume in osteoarthritis, while none of these tissues increase in volume in aging. A pigmentary change occurs in aging, but does not appear in osteoarthritis. Ultimately eburnation generally occurs in osteoarthritis, which is not seen in aging. Although new bone formation occurs in aging, osteophytes do not occur in osteoarthritis without cartilage and subchondral bone changes. Changes in subchondral bone associated with osteoarthritis are not seen in normal aging. The water content of cartilage increases very early in the osteoarthritic process and is not significantly different in young as compared to old cartilage.[5] Additionally, the synthesis of Type II and small amounts of Type I collagen increases 4 to 20 times in osteoarthritis and is accompanied by increased synthesis of proteoglycans.[6]

Although osteoarthrosis and degenerative joint disease are sometimes used designations, most rheumatologists today prefer the term osteoarthritis because inflammation is present to some degree in virtually all patients, and occasionally it is very severe in intensity.[7–9] In one study of osteoarthritic patients, 75 percent clinically showed some component of inflammatory changes.[9]

Although osteoarthritic joints are generally thought to have gradual progression with increasing morbidity and disability, the evidence for reversibility is increasingly impressive.[10] Radiographic evidence of spontaneous recovery of the joint space has been reported.[11] The mechanism by which this occurs is not known but presumed to be an increase in synthesis that exceeds enzymatic degradation of the cartilage. Various operations such as osteotomies and arthroplasties that result in a shift of the load-bearing segment of the femoral head to another site have, in some patients, resulted in apparent increased cartilage production and healing of osteoarthritis of the hip.[12]

Although it was believed that cartilage cannot regenerate itself, recent evidence clearly demonstrates that chondrocytes can and do divide and synthesize the macromolecules of cartilage at a greatly increased rate.[13] Not only do chondrocytes replicate and increase their rate of synthesis of cartilaginous macromolecules, but also there is an accelerated formation of degradative enzymes as well.[14–16]

Treatment

The overall treatment objectives for patients with osteoarthritis are enumerated in Table 1, next page. The sooner treatment is begun in the pathogenesis of osteoarthritis the more effective it will be with greater possible chance for reversing the process. The components of an effective therapeutic regimen are listed in Table 2, next page. Although all will be discussed herein, some will be covered in greater detail in subsequent articles of this series on osteoarthritis.

Drug Therapy

At times the chronic pain of osteoarthritis can be relieved by analgesic compounds, but generally the nonsteroidal antiinflammatory drugs (NSAIDs) are more effective as they also counteract the secondary inflammation that punctuates osteoarthritis.[17] Although nonsteroidal antiinflammatory drugs as a group demon-

Table 1. Treatment Objectives in Osteoarthritis

1. Relieve symptoms of pain and stiffness
2. Minimize functional loss
3. Deter progressive cartilage degeneration

Table 2. Components of Osteoarthritis Treatment Regimen

1. Drug therapy
2. Patient education
3. Diet
4. Rest and exercise balance
5. General medical management

strate the ability to inhibit such mediators of inflammation as prostaglandins, there appear to be important differences between agents in immunologic, pharmacologic, biochemical, and analgesic actions.[18] A substance, presumably a prostaglandin, inhibits articular cartilage metabolism by suppressing synthetic rates of chondrocyte cultures.[19] NSAIDs may alleviate arthritis by blocking this substance as well as traditional mediators of inflammation.

Although aspirin was the first agent used in the treatment of osteoarthritis, for a number of reasons it is being less frequently used as initial therapy than some of the newer agents. One of the difficulties with salicylates is that the range between serum levels required for maximal antiinflammatory effect (15 to 25 mg per dl) and that at which toxicity occurs (above 30 mg per dl) is so narrow. Additionally, because of the "pain-inflammation gap," to obtain antiinflammatory as well as analgesic effects it is usually necessary to administer between 975 to 1300 mg of aspirin four times per day. Patient compliance is found to be easier with some of the newer agents requiring only once or twice-a-day dosages.

More recently there also has been a concern with the possibility that salicylates may interfere with cartilage metabolism. *In vitro* inhibition of glycosaminoglycan synthesis by salicylate is much greater in osteoarthritic than normal cartilage.[20] Salicylate affects articular cartilage *in vivo* if a serum salicylate level of 20-25 mg/dl is achieved as the degeneration of femoral articular cartilage in dogs caused by immobilization is aggravated.[21] Further evidence of an *in vivo* as well as an *in vitro* effect comes from another experimental canine model of osteoarthritis.[22] In rat and porcine costal cartilage and in human and canine articular cartilage, salicylates corresponding to therapeutic serum levels have been shown to suppress chondrocyte glycosaminoglycan and proteoglycan synthesis.[23–26]

Similarly, *in vitro* studies with normal canine articular cartilage demonstrated that ibuprofen and fenoprofen reversibly and selectively inhibited net proteoglycan synthesis in a concentration-dependent manner.[27] Indomethacin and sulindac sulfoxide had no effect, and sulindac sulfide stimulated synthesis. Experiments with pharmacologic (25 μg/ml) and therapeutic levels (5 or 10 μg/ml) of piroxicam in porcine explant cultures revealed no consistent effect on cartilage proteoglycan catabolism.[28] Similarly, therapeutic concentrations of piroxicam had no significant adverse effect on chondrocyte glycosaminoglycan, protein, or collagen synthesis. Flufenamic acid and phenylbutazone administered *in vivo* have been demonstrated to suppress glycosaminoglycan synthesis in rat costal cartilage.[29]

In addition to varying effects on chondrocyte synthesis with different drugs, there are demonstrable differences in cartilage catabolism, which may be equally important in osteoarthritis. Sodium meclofenamate and indomethacin have no *in vitro* effect on the synthesis, activity, or release of chondrocyte proteinases (catabolins) by peripheral blood mononuclear cell-conditioned medium.[30] In the same laboratory, piroxicam *in vitro* had suppressive effects on both the synthesis and/or activity of catabolins derived from peripheral blood mononuclear cell cultures and rheumatoid arthritis and osteoarthritis synovium.[31]

The general approach to choosing a nonsteroidal antiinflammatory drug is to determine which drug provides the most relief of symptoms and is well tolerated by the individual. Not infrequently one patient will have an excellent response to a given agent while another gets no benefit at all. It has been shown that differences among patient responses to four chemically similar compounds were much greater than the differences between the compounds.[32] Patient-physician confidence is greater if patients are warned that several drugs may have to be tried sequentially to determine which is the best agent for them. The nonsalicylate NSAIDs currently available are listed in Table 3. Since

Table 3. Nonsalicylate NSAIDs Used in Osteoarthritis

Chemical Name	Trade Name	Dosage Frequency
Piroxicam	Feldene	Q.D.
Sulindac	Clinoril	B.I.D.
Naproxen	Naprosyn	B.I.D.
Indomethacin	Indocin-SR	B.I.D
Tolmetin	Tolectin	T.I.D.
Meclofenamate	Meclomen	T.I.D.
Ibuprofen	Motrin	Q.I.D.
Fenoprofen	Nalfon	Q.I.D.

osteoarthritis is a truly chronic disease, narcotics should be avoided. Nonnarcotic analgesics may be useful, particularly with a patient who has developed a peptic ulcer associated with a nonsteroidal antiinflammatory drug, until the ulcer has been demonstrated to have healed and another agent may be considered. Acetaminophen is the most commonly used, but the total daily dose should not exceed 2.6 gm, as toxic hepatitis can be produced with larger doses, particularly in the setting of underlying liver disease. Propoxyphene hydrochloride, prescribed three or four times a day, is an effective analgesic for short-term pain relief. Although it has a minimal risk of dependence, there is documentation of its addictive potential, and withdrawal can produce insomnia, nausea, vomiting, irritability, agitation, and seizures. Consequently, it too should be used judiciously.

If a single joint is disproportionately swollen or inflamed, synovial fluid aspiration is necessary to rule out such disorders as septic arthritis and microcrystalline synovitis (gout or pseudogout). After these have been excluded, particularly infection, the acute joint inflammation can often be controlled by the intraarticular injection of glucocorticoids. These directly administered steroids probably decrease the chronic inflammation through their influence on the network of increased vascularity.[33] If intraarticular steroids are required more than several times a year in the same weight-bearing joint, an alteration of drug therapy may be indicated, or if other joints are well controlled, it suggests that the patient may be a candidate for surgical intervention.

Drug Toxicity

Particularly in a disease like osteoarthritis, which is not only nonfatal but nondebilitating in the majority of patients, one must be very concerned about the safety of drug therapy. For many rheumatologists, this has curtailed the use of phenylbutazone and oxyphenbutazone in the treatment of osteoarthritis. Toxic marrow reactions, including agranulocytosis and aplastic anemia, which may be fatal, have been reported with these agents.[34,35] This complication led the list in the series of adverse reactions to nonsteroidals reported to the Committee on Safety of Medicines.[36] In an eight-year interval there were 294 deaths reported with phenylbutazone or oxyphenbutazone, and 204 of these were due to bone marrow toxicity. A subsequent survey estimated mortality at 17 deaths per 100,000 patient-years with phenylbutazone and 40 with oxyphenbutazone, with an administered average dose of 300 mg per day.[37]

Compared to other nonsteroidal antiinflammatory drugs prescribed to a similar extent, phenylbutazone and oxyphenbutazone account for a disportionately large number of fatal blood dyscrasias—probably over one third of those seen, excluding agents used in cancer chemotherapy. In the past year Weber compared the total adverse drug reactions of the nine nonsteroidal antiinflammatory drugs most recently marketed in the United Kingdom.[38] The three drugs with the least number of serious adverse reactions per prescriptions written were piroxicam, diflunisal, and sulindac in that order, and all three are available in the United States.

Patient Education

At the beginning of therapy it is important to educate patients and their families about the nature of their disease and what they can reasonably expect from treatment. In a disease such as osteoarthritis, it is important to emphasize that rarely do patients become crippled or incapacitated. This hopeful optimism must be balanced with the reality that not all their pain may be eliminated: they should eschew medical overtreatment or joining the many Americans spending millions of dollars a year on arthritis quackery. For most, a good, open relationship with their physician provides sufficient psychological support, but occasional patients will require added input from social workers, vocational counselors, or psychiatrists.

Diet

Obesity appears to be significantly correlated with osteoarthritis of the knee and unrelated to the incidence of hip involvement. Despite the fact that obesity has not been definitely established as a pathogenetic factor, when the hips, knees, or back are involved, it is prudent to decrease the abnormal forces on load-bearing cartilage, and often there is concomitant symptomatic improvement. Other than weight reduction, there is no demonstrable evidence that dietary manipulation has a role in the management of osteoarthritis. It should be kept in mind, however, that many elderly people do not have a balanced diet, particularly if they have some functional loss impeding their ability to prepare adequately balanced meals. In such cases vitamin supplementation as well as social service intervention is indicated.

Rest and Exercise

The goals of physical therapy are to decrease pain and stiffness, increase range of joint motion, and increase the strength of involved muscles, particularly those around the knee, to increase stability and help absorb the shock of repetitive load bearing. Cartilage

absorbs relatively little of the impact of impulse loading; bone bears the brunt of it. The major protective mechanism occurs through reflex muscle contraction and flexion of the involved joints that absorb part of the stress rather than its reaching the cartilage and subchondral bone. Maintenance of muscle strength is therefore essential to the management of these patients.

Other benefits of a well-designed exercise program are not as obvious. In experimental arthritis in rabbits, it has been demonstrated that with a regimen of passive exercise the cartilage tended to heal suggesting that mechanical stimulation is a positive healing force.[39] In patients with juvenile polyarthritis, healing of the hip joint with increase in the joint space and marked clinical improvement occurs after a vigorous and extensive exercise and physical therapy program.[40]

Exercise programs for patients with osteoarthritis should be designed with several factors in mind. Activity, weight bearing, and use of the involved joints is encouraged so that the cartilage is mechanically stimulated to promote healing. Generally three to six hours of activity is recommended as long as pain does not last for more than an hour after such exertion. Three to four hours of rest is also recommended to allow rehydration and hyperhydration of the cartilage.[41]

Alteration of work patterns, such as sitting rather than standing, may be necessary to decrease the stress of chronic occupational activities. At time, other types of behavior modification may be necessary such as the curtailment or discontinuation of certain sports, such as jogging or tennis, if particular joints are being overused. Designing an appropriate physical therapy program may require a multidisciplinary team effort to individually tailor the therapy to each patient, taking into consideration such factors as strength, radiographic changes, the severity of the articular problems, and coexistent medical illnesses.

General Medical Management

In the treatment of patients with osteoarthritis, management of other general medical problems is also important. For example, osteoarthritis is more common in diabetic patients and approximately one quarter of hypothyroid patients have calcium pyrophosphate deposition disease, which may contribute to accelerated cartilaginous damage. Almost any endocrine disease has ramifications for osteoarthritis, since estrogen, androgen, growth hormone, insulin parathyroid hormone, thyrotropin releasing hormone, thyroid stimulating hormone, and thyroid hormone influence the regulation of connective tissue cells.[4]

Although osteoarthritis is not a systemic disease, occasionally there are complications outside of the joints that need to be recognized and appropriately managed. With significant involvement of the knee, the posterior aspect should be carefully examined for the presence of popliteal or Baker's cysts. Popliteal cysts are caused by the increased intraarticular pressure resulting in herniation of the synovial membrane through the posterior capsule and may dissect down the calf and simulate thrombophlebitis or the so-called "pseudothrombophlebitis syndrome."[43] Arthrography will delineate the presence and extent of cyst formation, but in some cases venography also will be necessary to exclude secondary phlebitis resulting from venous compression and hemostasis. Generally such cysts respond to intraarticular injections of steroids and several days of bed rest. Rarely, refractory cysts will require excision, generally performed with concomitant synovectomy of the knee to prevent recurrent cyst formation.

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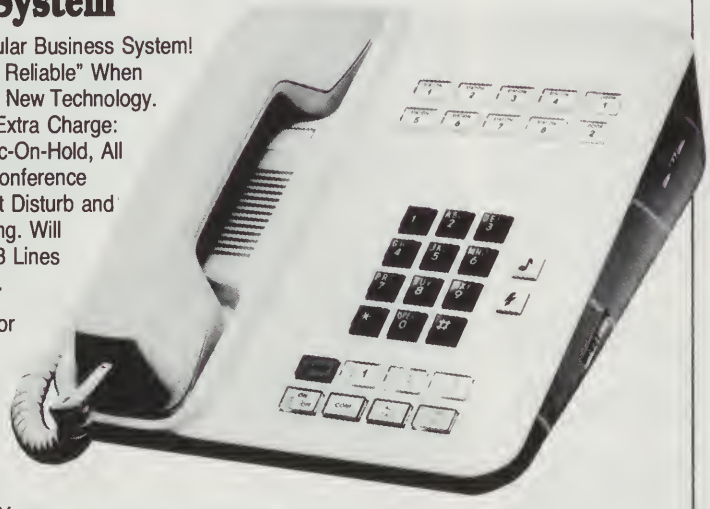
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Unsuspected miliary tuberculosis presented and was diagnosed as a late infection of the total hip replacement but was recognized only after removal of the prosthesis. Slow healing of the flail hip occurred with combination antituberculous chemotherapy.

Miliary Tuberculosis Masquerading as Late Infection in Total Hip Replacement

MICHAEL L. LEVIN MD

Dr. Levin, Assistant Professor of Medicine, Johns Hopkins University School of Medicine, was Head, Division of Infectious Diseases, Sinai Hospital of Baltimore, Inc.

Recently, miliary tuberculosis has decreased in frequency. Patients who develop the disease are older and present with an undiagnosed illness.[1] In such patients, the initial chest x-ray may be interpreted as normal. Thus, the first sign of disseminated mycobacterial infection may present in an extrapulmonary site. Prompt diagnosis and treatment are vital for patient survival. Abdominal organs and lymph nodes are the more common sites from which the diagnosis is established. An unusual presentation, that of a nonhealing, delayed infection in a total hip replacement was the clue toward establishing the diagnosis of miliary tuberculosis in one such patient.

Case Report

In 1975, a 75-year-old, native-born Israeli patient sustained a right hip fracture, which was treated by open reduction and internal fixation. She developed severe right hip pain; x-rays revealed aseptic necrosis of the femoral head.

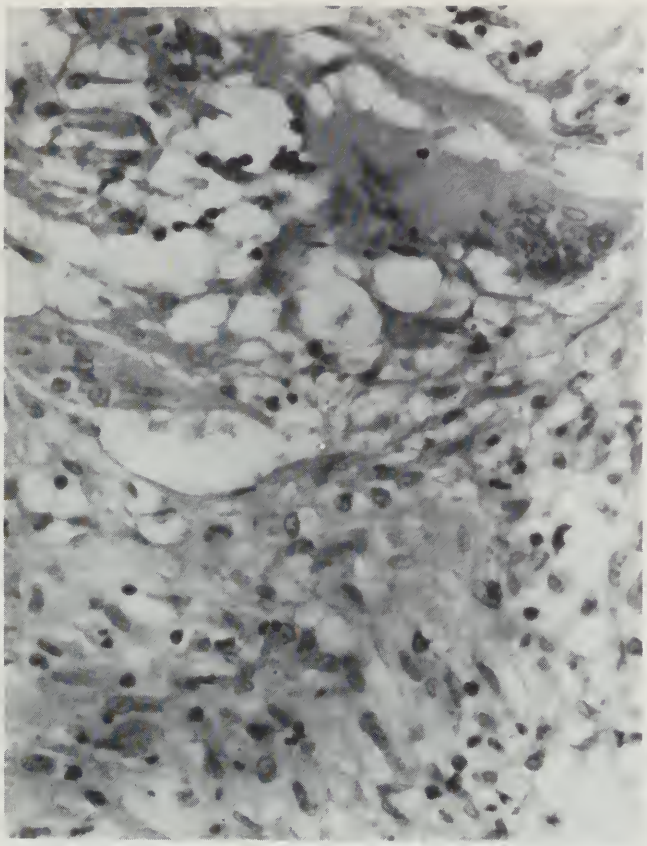
In September 1977, under spinal anesthesia, she underwent removal of a Jewett nail and insertion of a CAD Charnley-Mueller total hip replacement because avascular necrosis and malunion of an intertrochanteric fracture of the right hip with posttraumatic osteoarthrosis. Preoperative chest x-ray revealed "bibasilar minimal fibrosis; right peritracheal, hilar and lower lobe calcified granuloma, and right costophrenic angle blunting compatible with either minimal pleural fibrosis or small effusion and healed right rib fractures."

At surgery, perforation of the Jewett nail into the posterior aspect of the acetabulum and nonunion of the fracture were noted. Ten units of whole blood were required intraoperatively. Blood pressure finally stabilized at 50 mgHg. Wire mesh was needed to reinforce areas of the nonunion. The femoral component was cemented in place with Methyl methacrylate. The greater trochanter was reattached using the basket-wire technique of Charnley. Erythromycin was used for six days. Avitene was used to stop bleeding on several occasions. The wound was "copiously irrigated with Polymyxin-Neosporin solution."

The patient made a seemingly uneventful recovery. She was vigorously active, without symptoms referable to that hip for the next 30 months. In March 1980, she developed a six-week history of anorexia, fatigue, weight loss, and drenching night sweats but without localizing signs or symptoms. There had been no preceding trauma to the hip, intercurrent illness, use of steroids or antibiotics, nor awareness of fever. The day prior to Sinai Hospital admission, she described her first awareness of a fever (38.5°C), associated with right hip tenderness but without redness of fluctuance in that site. The initial white blood count was 14,000 and erythrocyte sedimentation rate was 55 mm/hr. A left iliac crest marrow clot and biopsy revealed slightly hypercellular marrow with mild increase in both the myeloid and erythroid precursors. Megakaryocytes and plasmacytosis and several granulomata without cells foreign to the marrow were described. Special stains for fungi and AFB were noncontributory. Hip x-ray, thermogram, and Technitium bone scan all suggested an inflammatory process in the right femoral shaft, in the region of the previous prosthesis. Again chest x-rays revealed old paratracheal calcification of granulomatous diseases. The patient denied previous exposure to tuberculosis or tuberculin skin testing. However, she was born and raised in Jerusalem, an area where tuberculosis was endemic in the beginning of this century. Examination failed to reveal surrounding lymphadenopathy, fluctuance, or erythema of the right hip.

Initial blood cultures grew Staphylococcus albus. The patient was placed on intravenous anti-Staphylococcal antibiotics and in April 1980 was transferred to Good Samaritan Hospital. Incision and drainage of 100 ccs of a pus-filled abscess that traced anteriomedially around the femur (in which the trochanter wires were sitting) were noted. At surgery, the prosthesis was not loose. No tracking into the femur was noted, and the prosthesis was left in place. However, the wires were removed from the greater trochanter. The wound was left open with Betadine packing, and for two weeks Cephalothin was administered. Aerobic and anaerobic cultures from the hip were unrevealing. Two weeks of oral Keflex was prescribed. By discharge, 50 days later, the wound had closed, leaving a half-inch deep sinus tract. Chest x-ray was read as "minimal interstitial prominence." WBC was 11,600, and the hematocrit was 36% after a two unit transfusion.

In August 1981, a right hip x-ray confirmed dislocation of the femoral prosthesis from the acetabular cup. Chronic "healed" osteomyelitis of the proximal femoral shaft was described previously, and no soft tissue swelling was noted. She underwent removal of the THR including both acetabular and femoral components as well as multiple fragments of bone and soft tissue. Microscopic examination revealed "fibrosis, chronic inflammation with an area of granuloma with caseation" in which were present acid-fast bacilli (see photomicrograph, next page). Anaerobic, intraoperative hip cultures were negative. Five days later, the aerobic cultures grew exquisitely sensitive Staphylococcus epidermides.



Photomicrograph of hip showing Langerhan's giant cell and epitheloid granuloma formation.

She was treated for 24 hours with Nafcillin, followed thereafter with oral Dicloxacillin.

The patient was discharged to a nursing home where antituberculous therapy was initiated, using Isoniazide hydrochloride, Rifampin, and Streptomycin. Liver function abnormalities occurred after two months of therapy, which prompted a two-month hiatus. Streptomycin was discontinued after the first three and one-half months of therapy. To date, she has completed uneventfully more than two and a half years of a three-year course of antituberculous chemotherapy. The flail hip has closed slowly. The chest x-ray remains unchanged.

Discussion

In 1977, McCullough[2] reported the first case of tuberculosis as a late complication (seven years) of total hip (Ring Prosthesis) replacement. No manifestation of active, systemic tuberculosis was described in that patient. Chest x-ray was negative. However, calcified mesenteric nodes noted on abdominal x-rays were thought to be the focus of a residual tuerculous infection that with reactivation, resulted in tuberculosis as a late complication of total hip replacement. The antituberculous therapy resulted in a cure without removal of the prosthesis in that case.

In 1979, Johnson and Owen[3] described two patients who developed reactivation of hip tuberculosis twelve months after total hip replacement (Charnley arthroplasty). Forty-two and 37 years previously, as children, both patients had been treated conservatively without antituberculous therapy for tuberculosis of the hip. The implant was removed in one patient and was expected to be removed in the other patient.

The three patients and the one described in this report: (a) initially cultured Staphylococcus from the site of their total hip replacement infection; (b) were treated with parenteral anti-Staphylococcal antibiotics; (c) failed to heal despite these efforts; and (d) only later, after M. tuberculosis was cultured from the nonhealing arthroplasty wound site, was the etiologic agent responsible for these late infections identified.

Although the patient in this report was asymptomatic at the time of total hip replacements, she had three factors suggesting chronic infections: a chest x-ray demonstrating an old granulomatous disease; a bone marrow examination demonstrating granulomata; and evidence of infection in the diseased prosthetic hip. It is proposed that with reactivation of an old primary pulmonary tuberculous site, the tubercle bacilli entered the circulatory system and resulted in miliary dissemination of the microbe. The hip prosthesis, as a foreign body, increased the risk for that site to become a nidus of infection for hematogenously disseminated mycobacteria. In this case, it also served as the anatomic site from which the diagnosis of miliary tuberculosis was established. An alternative explanation could involve surgical disruption of the granulomatous marrow with secondary seeding of mycobacteria from there to the newly placed prosthesis.

Review of the pathology slides of the initial orthopedic procedures failed to reveal any evidence of unsuspected active tuberculous infection of that joint.

At least one report[4] describes an event where a total knee was replaced in an unsuspected active tuberculous joint that previously had been subjected to steroidal infections. That patient responded well to systemic antituberculous therapy without need for removal of the prosthesis.

It was suggested by Kim *et al.*,[5] that preoperative antituberculous therapy may be beneficial for those patients undergoing replacement arthroplasty using a Charnley prosthesis in known old tuberculous disease of the hip. They describe twenty patients whose tuberculous joint disease was thought to be quiescent for years, but whose bone demonstrated characteristics of old osseous tuberculosis. They also placed Kanamycin in the bone cement during arthroplasty, although no evidence of its benefits is documented.

Conclusion

This case of miliary tuberculosis, diagnosed as a late infection of the total hip replacement, was recognized only after removal of the prosthesis. Slow healing of

the flail hip occurred with combination antituberculous chemotherapy.

Acknowledgment

Howard Dorfman MD, Pathologist-in-Chief, Sinai Hospital, reviewed all slides.

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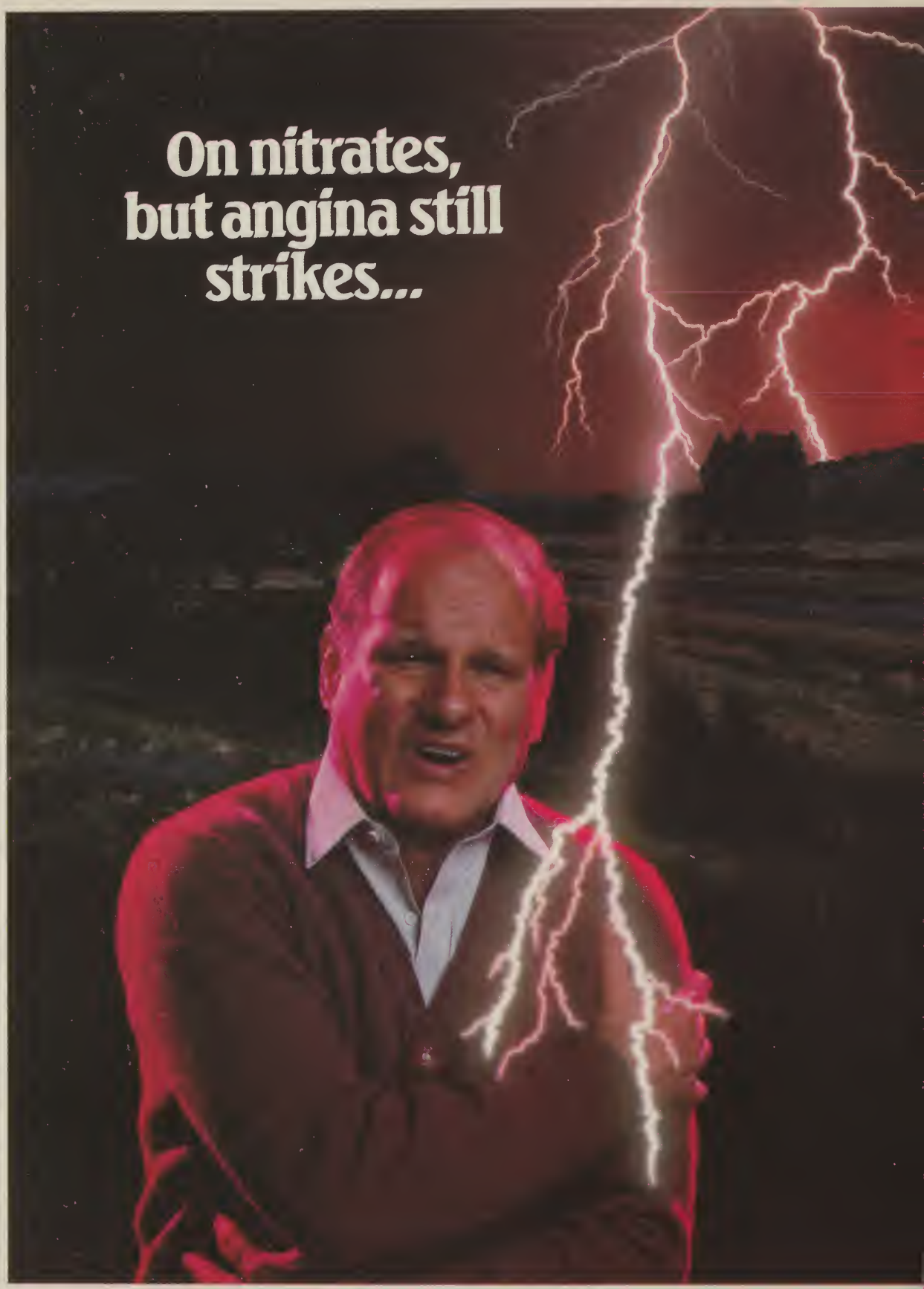
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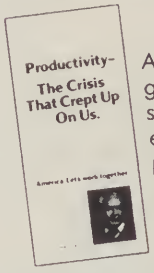
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The practice of medicine is a complex challenge to the average practitioner, and one tends to forget that one's colleagues and their families are potential (or past) consumers within the health care delivery system.

I had no particular background as either a provider or consumer of services for impaired physicians but happened to be in the "right place at the right time" as a medical director in a hospital. Later I was co-opted to the committee on physician rehabilitation.

Supervision of the Impaired Physician in a Clinical Practice Setting

JAMES P. G. FLYNN MD

Dr. Flynn is a *MMJ* Editorial Board member and former member of Med-Chi's Committee on Physician Rehabilitation.

There is increased awareness of the impaired physician among colleagues, consumers, and other members of the health care delivery team. Much has been written concerning the incidence and/or prevalence of impairment, and precise protocols exist on how to identify, confront, and deal with such individuals. Great strides have been made in therapeutic management and the restoration of the physician, spouse, and family members in the "at risk" population.

The following thoughts deal specifically with the physician who has completed most of the prescribed course of therapy, is in need of supervision in his or her work setting, and is hoped to have the potential to return to productive, unsupervised practice in the community at large.

As with any area in the practice of medicine, communication among the principals involved in supervision of the physician must be maintained at all times. Those supervising the therapeutic regimen must make clear to the participant the goals of the program. The physician or institution that will supervise the impaired physician's practice must establish clear definitions of the limitations within that practice setting, in the potential duration of supervision, and the understanding that information concerning the person's progress (or lack of progress) will be shared.

The physician placed in the supervised setting should be required to make formal application for employment, completing all necessary forms such as credentialing documents, references, and descriptions of past work experiences and situations that may have landed the person in his or her particular predicament. This information should be reviewed and approved formally by the credential and other appropriate committees, and privileges should be granted to the physician to practice within the new setting.

It is most important to notify the staff (new colleagues) of the reasons leading to this episode of employment. If this does not occur, embarrassing situations may arise. Very clear goals must be defined before the person is oriented to the new work setting. Particular emphasis must be placed on timekeeping, appearance, involvement in committee work, and attendance at conferences and continuing medical education programs. Any deviations will be considered as signs of potential failure. It is worthwhile indicating at this stage that if deviation occurs, the matter will be corrected quickly. Formal written notification will be made to the physician under supervision as to what was unsatisfactory and what is expected to rectify the situation. This should be placed in the credential folder with the understanding that it may be removed when the situation is corrected.

A major problem experienced by the physician under supervision is returning to work in a structured environment. Prior to commencement of the therapeutic program, the person may have led an unstructured existence, and previous practice settings may have been sporadic with little long-term commitment to the patient or to family members.

As time goes on and the person develops more confidence and familiarity with the new work setting, problems may arise. The very fact that the individual stays out of trouble and is doing what is normally expected from a physician may be interpreted by the person under supervision as synonymous with completion of the program. It has to be made very clear that these are just some of the steps on the road to returning to practice in some other setting. Great care must be taken to insure that the physician under supervision does not use the work setting as a therapeutic environment or thrust his or her problems upon patients under his or her care. A return of confidence in working with patients and in dealing with staff members will be punctuated from time to time by overreaction, in many instances reflected by sloppiness in writing notes, nonattendance at committee meetings, and tardiness.

After settling into the new work environment, complying with guidelines, achieving some goals, and taking reasonable care of patients, a return of clinical competence may provide overconfidence and a premature request to return to practice within the community. The supervisor also should be alert when the person under supervision wants to be treated like his or her colleagues if things are going well but has a multitude of "health problems" when defined goals are not achieved. Another problem is when the individual does not realize that he or she has responsibilities to the institution or organization and can't differentiate these responsibilities from the therapeutic goals laid down by those supervising his or her return to recovery in his or her overall health status.

The reaction of the administrative staff, nursing personnel, and other employees is significant. In this society the physician is often put on a pedestal, admired and envied. When this image is shattered by the arrival

of a physician who has had a variety of difficulties, there may be an expression of apprehension, horror, anxiety, and loss of confidence in the profession as a whole. To correct this, much is left on the shoulders of the person responsible for supervising the physician as well as on the impaired physician, who has to prove that the difficulties are transient and, like any other situation, can be improved. Noncompliance or deviation from initial goals or objectives of the program often are first brought to the attention of other staff members by patients when the physician does not make rounds or does not share an empathic relationship with the patients or family members.

It is important to sit down and review the various goals and progress at specified periods of time; on some occasions there will be little to report or discuss except continued progress. Reports should be sent to the referring source at regular intervals, and those making the initial referrals should be encouraged to come to see the physician in the new work setting. Academic goals should be defined, aside from getting the necessary number of credits to continue licensure. An individual completing residency training should be encouraged to seek board certification or, at some time in the future, attend some formal continuing medical education programs that have measurable (objective) outcomes.

One must remember the importance of rehabilitating impaired physicians. This may be more challenging in the future with the anticipated glut of physicians. It is incumbent upon the profession to continually review and revise strategies that may be available to help return impaired physicians to the mainstream of practice as appropriately as possible.

Acknowledgments

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Pelvic Inflammatory Disease (PID) is a clinical syndrome caused by microorganisms ascending from the vagina and cervix to the endometrium, tube, and contiguous structures. Rarely, the infection may be blood borne, particularly with unilateral infections.[1] Salpingitis is the "hallmark" of this syndrome.

Current Approach to PID

NORMAN LEVIN MD

Dr. Levin is Director of Education, OB/GYN; Co-Chief, OB/GYN; Maryland General Hospital, Baltimore, MD.

During the past two decades, there has been an unprecedented rise of PID apparently due to widespread changes in sexual attitudes and behavior. It is estimated that one million new cases of PID occur in this country each year. The highest incidence occurs in the 15 to 24-year-old category with a peak of 20 per 1,000 per year.[2] Two hundred fifty thousand of these new cases are admitted to hospitals, and 150,000 have a surgical procedure.[3] Approximately 900 women a year die from this disease.[4]

Sequelae of PID

The sequelae of PID make it the most important infection in the United States in nonpregnant women of child-bearing age. Of women who develop salpingitis, at least 20 percent develop infertility. Those women who do achieve pregnancy have a six- to tenfold increased risk of ectopic pregnancy.[5] Westrom noted at laparoscopy that tubal occlusion was present in 12.8 percent of women after one episode of salpingitis, in 35 percent after two episodes, and in 75 percent after three or more such infections.[6] Chlamydial infections cause an increase in prematurity rate thereby increasing the costs to the obstetrical and neonatal inpatients astronomically.[7] Chronic pelvic pain and a 15 percent incidence of sacroiliitis can be a debilitating aspect of this syndrome approaching.[8] The total cost of care for patients with pelvic inflammatory disease is thought to be three billion dollars per year. This estimate excludes the cost of long-term sequelae such as infertility, pelvic pain, ectopic pregnancies, and those cases of prematurity due to infection.

Bacteriology

More than 20 microorganisms have been implicated in the causation of PID (Table 1). In the past, the traditional microbiological assessment was based on cervical cultures with the disease being classified as gonococcal or nongonococcal in origin. Currently, with more specific culture techniques of the cervix, urethra, rectum, endometrium and pelvic exudate, Chlamydia, facultative gram negative organisms, and anaerobes are being isolated. One of the most important conceptual breakthroughs in the approach to PID has been the realization that a large percentage of upper tract infections are polymicrobial and that cervical cultures alone do not adequately represent the offending pathogens.[9]

Westrom reported that GC was not the major pathogenic agent in Sweden. He reported 60 percent of the cases of salpingitis were caused by Chlamydia and 10 to 15 percent by mycoplasma hominis. Gonorrhea accounted for 15 percent of all PID.[10] The diagnosis was confirmed by laparoscopy and included appropriate cultures of pelvic exudates and fimbriated ends of the tube. Laparoscopy was performed within 24 hours of admissions and before treatment was started.[11]

McCormack stated that roughly 50 percent of cervical cultures of symptomatic women who come to urban clinics of the USA are positive for Gonorrhea. Negative cultures indicating nongonococcal infections are frequently due to Chlamydia.[12] Eighty-five to 90 percent of all tubo-ovarian abscesses are anaerobic in origin.[13]

Pathogenesis

The individual who has multiple sexual partners is more prone to this infection. An infected male partner with motile sperm is more likely to sexually transmit disease.[14] Individuals wearing an IUD are at double the risk for sexually transmitted disease.[15] Barrier types of birth control prevent infection by shielding the cervix. Oral contraceptives prevent infection by creating a less permeable cervical mucous reducing the penetration of spermatozoa and decreasing the incidence of PID.

With an increasing cesarean section rate, the incidence of postpartum infections of the generative tract has risen considerably. Invasive procedures such as elective abortions, uterine curettage, and hysterosalpingography may cause the spread of lower genital tract infection into the pelvic cavity.

Symptomatology

The onset of symptoms is more commonly associated with the menses in the presence of Gonorrhea than

Table 1. Bacteriology of PID

1. Chlamydia trachomatis
2. Neisseria gonorrhea
3. Mycoplasma Hominis
4. Urea Urealyticum (Mycoplasm T)
5. Anaerobes—Bacteroides, Peptococci, etc.
6. Streptococci (aerobic and anaerobic)
7. E. coli
8. Enterococci
9. Klebsiella
10. Pseudomonas
11. Haemophilus Influenzae
12. Actinomycocis
12. Clostridium Welchi

Chlamydia infection. Bilateral abdominal pain is generally present, being more severe with the GC variety than with Chlamydia. Forty percent of Chlamydia PID is associated with only vague lower abdominal pain, but Chlamydia causes more menstrual abnormalities. Febrile episodes are more commonly present in the GC than Chlamydia infections. Nausea and vomiting, dyspareunia, proctitis, and GU irritative symptoms may be present with any bacterial origin.[16]

The Curtis-Fitzhugh syndrome, first described in 1930, is associated with perihepatitis "violin string" adhesions between the anterior surface of the liver and the anterior abdominal wall secondary to salpingitis, causing upper abdominal pain.[17]

Since 1976, the Swedes have stressed that Chlamydial infections cause fewer symptoms. These patients are less likely to seek medical attention, thereby increasing the incidence of infertility.

Physical Findings

Physical findings include signs of peritonitis with bilateral lower abdominal spasticity and tenderness. Cervical motion tenderness is frequently noted, as is a purulent cervical exudate. Adnexal tenderness with or without palpation of pelvic masses is generally present. On bimanual exam, the pelvis feels "hot" and may be so even without high oral temperature. A mass may be palpable on rectovaginal exam. Some patients are acutely toxic with associated ileus and high temperature.

Laboratory Assessment

Cervical and endometrial cultures are more accurate than are gram stains. Gram stains are valuable but are positive in only 66 percent of the cases of Gonorrhea. Cell cultures for Chlamydia that are then scored by immunoperoxidase studies have a high degree of specificity.[18] The use of a wet-mount smear is a pragmatic approach in the clinician's office. If the patient has no increase in WBCs with a relatively clean slide, one is probably not dealing with pelvic inflammatory disease. The serum C reactive protein is elevated in 80 percent of the cases of PID but is nonspecific for infections of the generative tract. Leukocytosis with a sed rate above 15 millimeters is of value but, again, is nonspecific.

Cul de sac fluid, with a WBC count generally exceeding 30,000 is an excellent source for culture. WBC counts of less than 1,000 usually mean no infection. This fluid also can be analyzed for isoamylase (SGI) studies. With a normal generative tract, isoamylase will be present but is usually totally absent or considerably diminished in the presence of PID.[19] WBC counts of cul de sac fluid is much more pragmatic than isoamylase studies.

The gold standard of diagnosis is laparoscopy. In Westrom's study of 3,000 laparoscopies performed with an assumed diagnosis of pelvic inflammatory disease, there was a prelaparoscopic diagnostic error in 35 percent of the cases. Twenty-five percent of those cases in error had normal pelvic findings. The misdiagnosed cases included genitourinary infections, endometriosis, ectopic pregnancy, appendicitis, ovarian cyst, and Krohn's disease. Ectopic pregnancy and appendicitis accounted for 6.6 percent of the cases subjected to laparoscopy in this series.[20]

Noninvasive techniques such as ultrasonography do play a role in the diagnosis of tubo-ovarian abscesses and in following their resolution.

Indication for Hospital Admission

Criteria for admission to the hospital of a patient with PID include temperature above 38° Centigrade and/or failure to respond within 48 hours to oral antibiotics. Nausea and vomiting and/or dehydration are other justifications for admission. Since Burkman's study of IUD users demonstrated an estimated hospitalization rate 1.6 times higher than the non-IUD user, hospitalizing such patients early in the course of disease is reasonable. Certainly, the IUD should not be removed in a symptomatic patient without providing antibiotic coverage. Patients with pelvic abscess necessitating parenteral antibiotic therapy are best treated as inpatients.

Decisions of Therapy

Two basic tenets of antibiotic therapy of PID are that treatment should continue for a minimum of 10 to 14 days, and because of the polymicrobial origin of PID, proper drugs should be administered. The Center of Disease Control *1982 Guidelines for Sexually Transmitted Disease* recommend inpatient and outpatient regimens (Table 2, next page).

The interval between the onset of symptoms and initiation of treatment is extremely critical with emphasis on treatment within 48 hours of symptomatology. Those patients treated within 48 hours have a much lower incidence of tubal occlusion than women treated later in the disease.[21]

Sweet reported 17 Chlamydial infections treated with second and third generation cephalosporins with clinical cure in 13 of these patients. However, 12 of these 13 patients still had positive endometrial cultures for Chlamydia, emphasizing the need for more specific antibiotics such as Tetracycline, Doxycycline, and

Table 2. Center for Disease Control Recommendations for Treating PID

Hospitalized Patients	Ambulatory Patients
Doxycycline—100 mg. IV q 12 h and Cefoxitin—2.0 g. IV q 6 h for at least 4 d. Continue Doxycycline—100 mg. po b.i.d. for 10–14 d.	Cefoxitin—2.0 g. IM **or** Amoxicillin—3.0 g. po **or** Ampicillin—3.5 g. po **or** Aqueous procaine Penicillin G—4.8 mu IM **or** Spectinomycin 2.0 g. for Penicillinase producing GC **with** Doxycycline—100 mg. po b.i.d. for 10–14 d. **or** Tetracycline .5 g. q.i.d. × 10 d. **or** Erythromycin .5 g. q.i.d. × 7 d.—for patient unable to tolerate Doxycycline or Tetracycline
or	
Clindamycin—600 mg. IV q 6 h and Tobramycin or Gentamicin—2 mg./kg. loading, then 1.5 mg./kg. IV q 8 h for at least 4 d. Continue Clindamycin—150 mg. q.i.d. for 10–14 d	Precede all Penicillin Treatment with Probenecid 1 g. po
or	
Doxycycline—100 mg. IV q 12 h and Metronidazole—1.0 g. IV q 12 h for at least 4 d. Continue both po for 10–14 d.	

Erythromycin.[22] When a patient has a pelvic abscess, triple antibiotic therapy is generally used, with care to treat potential anaerobic organisms. Bartlett *et al.* have demonstrated the predominance of anaerobic bacteria in pelvic abscess formation.[23]

Today fewer total abdominal hysterectomies and bilateral salpingo-oophorectomies are being performed for ruptured tubo-ovarian abscess than 20 years ago. Current therapy with proper antibiotic coverage has markedly decreased the incidence of ruptured abscess requiring immediate surgery.[24] With the rupture of a tubo-ovarian abscess confined to one adnexa, unilateral adnexectomy is justified. When future childbearing is a factor, this therapy is adequate even if the other adnexa is inflamed without abscess formation.[25] Copious lavage of the entire abdomen with saline, proper drainage, and adequate postoperative antibiotic therapy will make this conservative approach more feasible. A pelvic abscess that persists 4 to 6 weeks despite some clinical relief necessitates surgery. Some of these masses may be neoplastic rather than infectious in origin.

With repeated crippling episodes of PID in a woman hoping to have children, a bilateral salpingectomy with attempts to conserve at least one ovary and the uterus is indicated. The emergence of *in vitro* fertilization and embryo transfer as fertility techniques influences the management decisions in these patients. This approach is advocated recognizing a high incidence of abnormal uterine bleeding and ovarian cyst formation after a bilateral salpingectomy with the uterus and ovaries *in situ.*

The role of tuboplasty for badly distorted tubes due to salpingitis is still very limited. Severe tubal disease with its resultant destroyed tubal epithelium and decreased tubal peristaltic activity generally causes infertility despite the achievement of surgical patency.[26] Should a small percentage of these patients get pregnant, there is an inordinately high incidence of ectopic pregnancies. Results of tuboplasty in the presence of mild disease are quite satisfactory particularly when one only has to perform lysis of adhesions. There is reason to believe that microsurgery plus the microsurgical techniques of gentle handling of tissue and meticulous hemostasis enhances the success rate of tuboplasty.[27]

Summary

Pelvic Inflammatory Disease is one of the most important infections of women of childbearing age. There is a progressive recent increase in incidence due in part to altered sexual habits. Major changes in the concepts of the bacteriology of this disease have occurred. Laparoscopy has contributed considerably to the accuracy in making the correct diagnosis. Antibiotic therapy generally should be broad spectrum because of the polymicrobial nature of this disease. New surgical concepts to conserve the childbearing function are being used more frequently.

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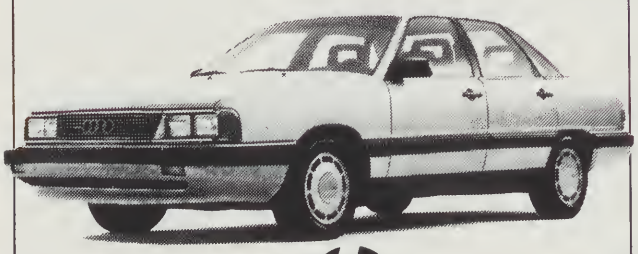
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At the request of the Baltimore City Medical Society's Board of Directors, the following position paper was prepared by John Meyerhoff MD, as Chairman of the City Society's Health Care Delivery Committee.

Health Care Costs—Past, Present, and Future

JOHN MEYERHOFF MD

Dr. Meyerhoff is Chairman, Health Care Delivery Committee of the Baltimore City Medical Society; Acting Chief, Rheumatology Section, Sinai Hospital of Baltimore; and Assistant Professor of Medicine, Johns Hopkins University School of Medicine, Baltimore Reprints: Dr. Meyerhoff, 2435 W. Belvedere, Baltimore, MD 21215.

Over the past thirty years there has been a dramatic increase in the proportion of the Gross National Product that is spent on health care. In 1950, $13 billion, or 4.5 percent of the GNP went to health care.[1] By 1982, the figures were $322 billion and 10.5 percent. Increasing health care costs continue to outpace the increases in the Consumer Price Index. While there is no clear consensus as to how much of the nation's resources should be spent on health care, and most Americans profess to be receiving good medical care,[2,3] it is clear that physicians and the public alike are concerned about the future cost of health care and their ability to pay for it. In a public opinion poll conducted by the Equitable Life Assurance Company, 50 percent of the public felt that "fundamental changes are needed to make [our health care system] work better."[4] The major problem seen by physicians and the public was the cost of health care.

This position paper will explain some of the reasons why health care costs have increased and, where possible, what is being done to reduce these costs. Only 20 percent of the health "dollar" is spent on physician fees with the rest going to hospitals, nursing homes, medication expenses, laboratory studies, and other expenses. About 75 percent of these costs are under the control of the physician. To a large extent however, public policy is responsible for the growth in the amount of money available to pay for the health care delivered in the U.S.

The Role of "Public Policy" in Health Care Costs

Increased Funding for Health Care Prior to the end of the Second World War a large amount of free care was given to the poor by physicians and hospitals. Physicians on the staff of many hospitals were required to spend time in the hospital inpatient and outpatient services providing free care to the indigent. Housestaff worked for close to nothing in exchange for their training. Thus a great deal of the health care provided was not only free, it also did not show up "on the books" in any accounting of costs of health care.

With the Hill-Burton Act in 1946, the government began to provide funds for hospital construction. The purpose of this program was to ensure access to health care by encouraging the construction of health care facilities that otherwise would not have been built. With the expenditure of $3.7 billion the government generated a total of $13 billion in hospital construction.[5] In the 1960s the federal government embarked on a program to increase the number of physicians in response to a similarly perceived lack of access to health care. Sufficient federal and state funds were appropriated to result in a doubling in the number of medical school graduates from 1965 to 1982.[6]

In 1965 the Medicare and Medicaid programs were enacted, converting much of the free care being delivered into paid-for care. These programs were enacted to assure access to the medical system by those who could not afford it. This increase in governmental funding of health care was matched by the growth of medical insurance as a fringe benefit of most jobs. As a result of these events, few if any patients are truly "self-pay" patients. This influx of money has changed the way hospitals are funded. For example, the percentage of the operating budgets of the nonprofit hospitals in New York City provided for by philanthropy decreased from 24 in 1940 to one percent now.[7]

The costs of the Medicare and Medicaid programs continue to increase at levels that are ahead of all previous projections. Medicare expenditures rose from $16.0 billion in 1977 to $39.9 billion in 1983 just for the hospital insurance portion.[8] The trust fund from which this portion of the program is paid is expected to go broke between 1989 and 1995, depending on how pessimistic one's assumptions are. Medicaid expenditures rose from $6.3 billion to $29.9 billion from 1972 to 1982. This is a compound annual growth rate of 16.9 percent. The growth in these expenditures exceeded the growth in federal and state revenue by 40 percent for this time period.[9]

The federal government also made the decision to provide transplantation or dialysis for everyone with end-stage renal disease (ESRD). In 1972 Congress was told that the cost for this program in 1976 would be $250 million. By 1976 the program was costing $500 million. The estimate for 1980 expenditures at that time was $1.3 billion. The cost of this program by 1982 was $1.8 billion.[10,11]

The major reason for the dramatic increase in this program was an underestimation of the number of patients who would enroll in the program. Through improvements in medical care the unit costs of renal transplantation and dialysis have not increased since the program started.[12]

Biomedical research also became a concern of the federal government. The amount of National Institutes of Health funding for both intramural and extramural research increased dramatically from less than $200,000 immediately after the Second World War to $82 million in 1955 to over $1 billion in 1968.[13]

All these programs have not only increased the amount of money spent on health care, but also they

have increased the amount of medical care being delivered to the public. The inclusion of "bad debt" in hospital rates is a "public policy" that is not always explicitly stated. This policy allows hospitals to provide care to those who can not afford it by charging patients who have health insurance more than their hospitalization cost. This is known as cost shifting. While this subtle form of "taxation" or income transfer may have decreased with the institution of the Medicare and Medicaid programs and the increase in private insurance programs, bad debt continues to be a problem for many hospitals.

Not all the implicit "public policies" that have increased the cost of health care produce direct increases in the delivery of health care. Postgraduate medical training (internship and residency) expenses also are included in the room rates of the teaching hospitals. These costs have increased dramatically. This is not because more service is being provided, but because these individuals are being paid a reasonable salary. Gone are the days when interns were given room and board and not allowed to marry. This policy has so far been continued in the new reimbursement schemes. Both the national Medicare/DRG system and the Maryland hospital reimbursement system have allowances for postgraduate educational expenses. Nonphysician employees of hospitals also used to be paid very poorly and are now receiving more reasonable salaries.

Unfortunately, there is a public policy that clearly increases the cost of providing health care without providing any direct or indirect increase in the amount of health care delivered in this country. It is implicit public policy in the United States that the medical malpractice insurance system is to be used not only as a way of reimbursing the patient who suffers from negligent care, but also as a method of indemnifying the patient who may have a poor outcome of nonnegligent care.

In 1960, $61 million was spent on malpractice insurance nationwide. In the next ten years this increased to $370 million.[14] In the next three years this amount almost doubled, and the latest figure is that the yearly costs of such insurance is $2 billion.[15] It has been estimated that in California (which may not represent the average state) malpractice premiums add $5 a day to the cost of hospitalization and $3 to each outpatient visit.[16] Five dollars a day represents perhaps one to two percent of the daily room rate for most hospitals. Three dollars a day is almost 14 percent of the average physician's fee for established patients.[17]

Inefficiencies in the Health Care Reimbursement System As a result of these changes medicine has become "big business" that has drawn large for-profit corporations into the health care field. While most businesses have clear-cut rewards for efficiency, the medical field has not in the past rewarded physicians or hospitals for being cost conscious. In fact, for most hospitals the rewards have been just the opposite. These policies of not encouraging efficiency were accepted as long as they were not too expensive.

For many years hospitals were rewarded on a "cost-plus" basis, which only encouraged the hospitals to increase costs. The other major system of reimbursement was one in which hospitals were reimbursed on the basis of their charges for each service. It is recognized now that these reimbursement systems have been major factors in increasing the cost of care delivered in hospitals.

It has become evident that much of the care given in hospitals can be delivered as well and much more efficiently outside the hospital. Nonetheless, the reimbursement policies of many insurance programs have had the effect of driving patients into the hospital. Many policies still cover only those expenses associated with hospitalization. This is in part a holdover from the early days of medical insurance where it was felt that if a patient was sick enough to be in the hospital, then the services provided were probably needed.[18] Moreover, with hospitalization the need for medical care was (and still is) more easily verified than when the care is delivered in a doctor's office. In addition, such a policy also will limit the amount paid by only paying for more severe illnesses.

However, sometimes when a patient would have incurred a large bill for outpatient services, the physician and patient would opt for hospitalizing the patient so that the patient's insurance would pick up the bill. As the technology of medicine advanced and the costs of this technology increased, this practice increased. The introduction of the CAT scanner (which was a very expensive single test) brought this practice into focus. Basically healthy individuals began to be admitted to the hospital overnight solely so that the individual's insurance would cover costs of the CAT scan. Now, in addition to paying the costs of the scan, the insurance companies were paying the costs of the hospital to provide the bed that the individual was occupying. This same process occurred with procedures that are now being done in "same day" surgical centers.

Another inefficiency occurred in the development of the reimbursement procedures of the health insurance companies. The unit of service developed was the surgical procedure. Under such a system the bias is to pay more for procedures (which again are more easily verified) than for nonsurgical medical care.[18] Such a system encourages unnecessary care of two types. First, there is the individual patient who may or may not need an operation that has known indications (that is, appen-

dectomy for appendicitis). The second type is the performance of procedures (that is, tonsillectomy for recurrent tonsillitis) that the medical community debates the need for.[19] It also encourages physicians to set charges for these procedures that do not represent the true cost of the procedure but rather the costs of the procedure plus pre- and postop visits, which might not be reimbursed by the insurance carriers.

These situations highlight what is perhaps the major inefficiency in the health care system that has developed since almost everyone now has insurance of some type. Usually neither the consumer of health care (the patient) nor the person who decides which resources are to be consumed (the doctor) has any financial incentive to hold down costs. An extra day, lab test, or x-ray in the hospital often has not cost the patient or physician anything. As noted above, hospitals were reimbursed in such a way that they had no incentive to discourage such practices. With the proliferation of "first dollar" insurance policies covering all an individual's health costs and policies that cover outpatient testing, this lack of incentive has spread to the practice of outpatient medicine.

Current Cost Trends

Hospital Costs From 1965 to 1979 hospital costs rose from 33 percent to 40 percent of the health care costs in the United States.[20] In approximately the same period hospital room charges increased 3.8 times, while the Consumer Price Index (CPI) increased only 2.2 times. Hospital costs were responsible for 42 percent of the increase in health care costs for the 1965 to 1979 period. It is because of this central role that hospital costs play in the cost of health care that the hospital is the focus of the attempts to control costs. As noted above, hospital costs have increased because the economic incentives were there to increase the cost of hospital care and the utilization of hospitals.

Physician's Fees While hospital costs were increasing so dramatically in the late 1960s and the 1970s, physicians' fees were essentially unchanged. As a percentage of health care expenditures, fees decreased from 20.2 percent to 19.1 percent. While the CPI went up 2.2 times, fees increased 2.4 times.[21]

Over the nine years from 1973 to 1982 the average net income for physicians decreased in inflation-adjusted dollars despite rising gross income.[22] Physicians' expenses during this time rose faster than income. While some of the increasing expenses were for personnel and technology, the explosion in malpractice insurance premiums noted above also played a role.

Nursing Home Expenses and the Care of Patients Over 65 Years Old Nursing home expenses increased from 4.9 percent of expenditures in the health care system in 1965 to 8.4 percent in 1979. Some of these expenses are not due to elderly patients but rather to individuals with acute problems requiring prolonged rehabilitation or individuals with chronic diseases requiring constant nursing care. However, 86 percent of nursing home care expenditures are for individuals over age 65. People over the age of 85 account for 35 percent of all days of nursing home care.[23]

Individuals over age 65 use more health care resources than those under 65. (The use of age 65 as a divider is clearly convention since the average 64-year-old is not significantly healthier than the average 65-year-old.) The over 65 population has higher hospital expenses ($869 vs. $370) and more doctor's visits per year (6.3 vs. 3.2) per capita than the 18 to 64-year-old population.

Thus as the population of the U.S. ages and the percentage of the population over 65 and 85 years old increases there will be correspondingly larger health care expenses. Already a third of the health care expenses of the over 85-year-old age group is spent in the last year of life for these individuals.[24] There may be further increases in this percentage if the public health education campaigns of the past 20 to 30 years concerning cigarette smoking, diet, exercise, for example, have the effect of further compressing illness into the last year(s) of life.

Methods for Reducing Health Care Costs

Clearly, new reimbursement methods are needed that will encourage both patients and physicians to use health care resources available wisely. These may include deductibles or other restructuring of health insurance benefits, development of newer health care delivery organizations, and the introduction of prospective reimbursement for hospitalization. Health care costs also can be reduced by delivering medical care in less intensive but equally safe settings, such as same-day surgery facilities.

Deductibles "First-dollar" coverage, as noted above, can increase utilization of health resources. One method of reducing this is to have a deductible or "coinsurance" on all health care expenditures. Ideally the deductible is small enough to allow patients to afford whatever care is needed but is high enough to discourage patients from asking for unnecessary care or testing.

The Rand Corporation has undertaken a $70 million study to investigate whether coinsurance will in fact reduce the utilization of health care resources.[25,26] From several papers they have written it is clear that people who paid for some of their health care had fewer hospitalizations and fewer office visits than those individ-

uals whose care was free. This decreased utilization was true whether the individual had a 25 percent, 50 percent, or 95 percent coinsurance rate. Those individuals who had totally free care cost the plan 50 percent more per year than the rest of the patients.[27] These studies suggest that elimination of first-dollar plans may result in significant savings of health care costs.

Restructuring Health Insurance Benefits The goal of deductibles is to make the patient a more discriminating consumer by giving him/her a financial stake in more cost-efficient care. Another approach is to give employees a choice of types of medical insurance (fee-for-service, HMO, for example) and a fixed number of dollars to spend on the insurance. The employee is then free to spend additional dollars of his or her own for more coverage or to buy less coverage and pocket the difference.

With a "doctor glut" in certain parts of the country, insurance companies and physicians have developed groups of physicians who have agreed to charge less for particular patients in exchange for the potential of increased numbers of patients. These additional patients usually will be individuals who have medical insurance through an insurance company that has sold a lower cost policy to an employer. This lower cost is generally achieved by restricting patients to those physicians who have agreed to charge less. Depending on whether these groups are set up by the insurance carriers or the physicians, they are usually known as either Preferred Provider Organizations (PPOs) or Independent Practice Associations (IPAs). These plans represent a dramatic change in the freedom-of-choice of physician that has been available in almost every health insurance plan in the country.

Prepaid Health Plans An alternative is to give the physician incentives to reduce costs. The most widespread way to do this is the prepaid health plan referred to as a prepaid group (PPG) or a health maintenance organization (HMO). For the purposes of this article the term HMO will be used for both systems. The most successful of these systems are the Kaiser-Permanente groups on the West Coast. They have been able to provide less expensive, quality care for many years.

In these prepaid systems the patient pays a set fee for a year's care. This fee is usually less than corresponding health insurance would cost. If the HMO can deliver care for less than they have been paid, then the HMO makes money. The physicians in the HMO are given incentives to reduce expenditures. Those plans that have been successful have reduced costs by reducing the hospitalization rate and by increasing the use of nonphysician professionals. Studies of prepaid group practices show that outpatient visits by patients are more frequent than in fee-for-service settings.[28,29] Since the patient has prepaid, these extra visits do not "cost" more; but they do represent an increased use of health care resources.

In neither the Rand Corporation study[30,31] nor other studies of HMOs[32,33] is it suggested that fee-for-service physicians are more expensive per outpatient visit or hospitalization. However HMOs have been successful in reducing costs by establishing prepayment systems that force physicians to change their behavior or lose money. It is logical then that a similar approach might work in reducing the growth in hospital costs or perhaps even reducing them.

Prospective Reimbursement of Hospital Costs The major determinants in the cost of a hospitalization are the overhead of the hospital and the utilization of hospital services by the patient. Under the developing prospective reimbursement systems for hospital services, hospitals will be reimbursed only a set amount for each admission to the hospital. The prospective part of the plan is that hospitals will be reimbursed this year based on what it cost to take care of a patient with the same illness last year. A hospital that can take care of the patient for less than that amount makes money and survives. A hospital that cannot do so loses money and presumably will close. Under this system shorter lengths of stay and fewer tests and procedures are encouraged.

This type of system is the DRG (Diagnosis Related Group) system that was instituted nationwide (except in four states) for all Medicare admissions as of October 1, 1984. It is much too early to tell if this system will save as much money as its proponents suggest. Under a prospective reimbursement system that exists in Maryland, the rise in health care costs has been less than in the rest of the United States.

Use of Less Intensive Facilities to Deliver Care Physicians, like other professionals, tend to practice in traditional fashions. This is certainly not always cost efficient. In the past patients who might need to be seen daily to observe the effect of a treatment or to have a series of tests might be admitted to the hospital. However, although a daily visit to the doctor's office or the diagnostic radiology department for a week by a patient may seem unusual, it is certainly cheaper overall than keeping the patient in the hospital for that week. Outpatient intravenous antibiotic therapy for patients requiring several weeks of therapy is beginning to be done. This requires the development of new services. Other sorts of therapies can be delivered less expensively without compromising patients' health. As a corollary, when patients are admitted to more intensive facilities (that is, hospitals) the time there should be efficiently used. Hospitals probably will need to truly become seven-day-a-week institutions.

Another recent development is the increase in the number of surgical procedures being performed in an outpatient or "same-day" setting. This change has come about in part because of the expense of keeping basically healthy patients in the hospital unnecessarily. In part it was due to recognition that the tradition of admitting patients to the hospital for these procedures was medically unnecessary. The federal and state governments have drawn up lists of procedures they will not pay for if performed in a hospital but will pay for if done in lower cost facilities. Similar lists of procedures have been developed that mandate patients be admitted on the morning of the procedure rather than the night before. The private insurance companies are beginning to offer policies with such restrictions as a way of lowering premium costs.

Patient Education As important as these structural changes in the financial incentives for hospitals, physicians, and patients, is the need for the medical profession to educate our patients, the public, how to be good consumers of medical care. This applies to both general information and disease-specific information. We need to teach patients what the role of lab tests and x-rays are in the diagnosis of disease. We also need to teach patients that not every illness needs to be treated with medications.

Several studies have shown that educating patients of all socioeconomic groups about specific illnesses and when physician intervention is needed can reduce the number of unnecessary visits.[34,35] In one study it was estimated that every dollar spent on education saved between $2.50 and $3.50 in health care costs.[36]

Caveats Concerning Changes in the Health Care System

Much of the remarkable change that has occurred in the health care system has been relatively easy to achieve because the system was inefficient and this inefficiency was unquestioned. It should not be expected that the next set of cost reductions will be as easy or free from cost to the health of the nation. Many of the methods of reducing health care costs outlined above are new and may not provide as large a reduction in costs as expected. Moreover, there may be undesired consequences to individuals and communities as a result of these changes of which the public is not yet aware.

Prepaid Health Plans HMOs have been touted as the best way to lower costs. As noted in several studies quoted above, they have lowered costs by reducing hospital utilization. As hospital use by all types of physicians decreases, HMOs may no longer be more cost efficient. Of the six HMOs available to employees of the State of Maryland, three are cheaper and three more expensive (to both the employee and the State) than the Blue Cross/Blue Shield High Option plan.[37] As the traditional fee-for-service system becomes more efficient, the HMOs may in fact become more expensive, particularly if they continue to offer free care once the initial prepayment has been made. Corporations that have begun to encourage their employees to join HMOs as a way of reducing health care costs may find out that they have in fact raised these costs.

Competition as a Force to Lower Costs The underlying assumption in the development of many of the new health delivery programs is that if consumers (either private individual or employer) are given the proper incentives they will purchase the most cost-efficient care. This presumes that the consumer will be able to get enough information to determine what is the most cost-effective care.[38] Consumer organizations and governmental bodies are beginning to publish physician fee schedules with listings by physician. This will allow a patient to determine what the minimum cost of a visit or procedure will be. What cannot be determined from such a list is how cost conscious a physician is. Since the office visit fee may be much less than the cost of laboratory and radiologic examinations and medications, visit fee schedules will not be enough to determine whether a physician properly uses these ancillary services. In addition, patient compliance (or noncompliance), which may relate to factors as varied as the physician's attitude toward patients or how long a patient has waited to see the physician, will affect the utilization of resources. Thus it should be obvious that even the most conscientious consumer will have difficulty being an informed consumer.

Increasing the number of physicians has been viewed as a means of lowering costs by increasing competition among physicians who would then presumably lower their fees. This probably has not occurred in the U.S. A Canadian study suggested that when there were more than 120 physicians per 100,000 population, per capita expenditures would decrease.[39] In 1950 there were already 140 physicians for each 100,000 people in this country.[40] Nonetheless, payments to physicians increased faster than the CPI from 1967 to 1979,[41] and it has been estimated that around 22 percent of the increase in these payments was due to the increasing number of doctors.[42] It is projected that from 1979 to 1990 that there will be a 17 percent increase in payments due to the larger number of physicians. Thus it seems unlikely that increasing the number of physicians will lower fees enough to make up for the cost of more doctors.

Hospital Costs As hospital use decreases, hospitals may begin to lose money and lay off employees and

close nursing units. There are several alternatives for the hospital at this point. It may choose to move to a more profitable location. It may encourage patients with certain types of illnesses to use it for inpatient care while it discourages patients with other diseases from being admitted. The hospital may even merge with another institution, or as a last resort it may close completely.

The uproar from Baltimore City over the proposed move of Maryland General Hospital to Baltimore County demonstrates the proprietary interest with which people view their local hospital. However, it is clear there are too many hospital beds in many areas and some hospitals will have to close and others may not be able to support every service that has been offered in the past. The regulatory emphasis has been to control the number of hospital beds by preventing hospitals from expanding. The time is fast approaching when the federal or state governments may start closing hospitals either directly or through financial incentives if the hospitals don't merge or shrink.

As noted above hospitals are big business and many of them are very well run. If there is a way to legally manipulate the system someone will find it.[43] Moreover, the new DRG system has not been proved as a way to reduce hospital costs. During the first two years a DRG based system was in place in New Jersey, hospital costs went up.[44] Whether this was a fluke due to the peculiarities of the New Jersey system is not known, but the new system did produce some dramatic changes in the services provided at individual hospitals.

One proposal to reduce health care costs is to decrease or stop the reimbursement that teaching hospitals have received to allow them to operate training programs for physicians. This suggestion is based in part on the fact that once a physician is finished training he or she will be well paid and can afford to repay any loans needed to get through the training period. Unfortunately, medical school is very expensive, and many graduates are starting their postgraduate training with large debts. There is some evidence that this phenomenon is driving physicians into those specialties that are very lucrative. If this continues, reducing reimbursements to teaching hospitals for teaching programs may be a shortsighted case of robbing Peter to pay Paul.

The teaching hospitals of this country are more expensive deliverers of health care than are the nonteaching hospitals.[45–48] It is not clear that they are always less cost efficient. The experience at several hospitals with both teaching and nonteaching sevices shows that the teaching services are more expensive.[49,50] At Stanford University however, this was accompanied by a lower in-hospital mortality rate on the teaching service, particularly for the sicker patients.[51] Other studies have also shown that teaching hospitals have sicker patients than the nonteaching hospitals.[52,53] These patients need the expensive technology and care that is characteristic of modern adult and neonatal intensive care units (ICUs), burn units, and oncology centers. This drives up the costs for all the patients in these hospitals. Thus, there will always be some higher cost hospitals that cannot cut costs without cutting services that a community needs. However, these hospitals cannot use this as an excuse for not being as cost efficient as possible in their operation.

Physicians' Fees and the Patient-Physician Relationship Since physicians' fees represent less than a fifth of all health care expenses, decreasing physician reimbursement will only result in modest savings. Moreover, the methods being used to lower physician reimbursement may have the effect of greatly disrupting the patient-physician relationship. The financial incentives that are the backbone of the PPO plans make it almost impossible for anyone who is not independently wealthy to continue to use a physician who is not a member of the particular PPO group associated with the patient's insurance carrier. Freedom of choice by patients of physicians in this situation is a falsehood since the insurance carriers do not want every physician in an area in the PPO. Thus a patient who is not buying his or her own insurance may have to change doctors when his employer introduces a PPO plan. While the patient may agree to this once, what will happen when his employer changes insurance carriers several years later to a firm that has a whole different group of physicians? Moreover, since each time a patient sees a new physician there is some duplication of services involved, frequent changes in physician may increase costs.

Nursing Home Care Costs There is a growing awareness that many individuals, particularly those dependent on Medicaid, are not receiving adequate nursing home care. Attempts to reduce expenditures in this area may be not only unsuccessful but also unwise. As noted above, the number and proportion of elderly in this country are increasing. This ensures that the number of dollars spent on custodial and rehabilitative care will have to increase dramatically. If further reductions in the Medicare and Medicaid payments to nursing homes occur then the problem that already exists will be exacerbated. Moreover, it is the patients with chronic illnesses who are most in need of access to the health care system to maintain their level of health.[54]

Quality of Care At some time, the health care of some individuals will suffer because their care will be too expensive for them to afford. It is possible that point in time has already arrived. The Rand study

showed that for some individuals, particularly those at high risk for some illnesses, free care resulted in better health and a decreased risk for future illness.[55] Moreover, a study of Californians whose Medi-Cal benefits had been terminated showed that control of blood pressure deteriorated enough to increase the risk of death by 40 percent.[56] Five of the 180 patients studied died, and in three of the cases the death seemed to be attributable to the loss of access to care or medicines.

The federal government (through the Health Care Financing Administration - HCFA) insists that it will not cut costs if medical care is endangered. Contracts for the new Peer Review Organizations (PROs) that are being set up to administer the new DRG system for the federal government have now been negotiated for each state and the District of Columbia. However, although some quality of care standards are in these contracts, in the negotiations for the contract for the PRO in Maryland it was clear that the primary concern of the HCFA negotiators was to reduce the cost of health care.[57] There is little evidence in any of the current review activities conducted by the insurance carriers that they are at all interested in improving care except as a byproduct of reducing costs.

Public Opinion Opinion polls have clearly shown that Americans want to decrease the costs of medical care as an abstract entity. They do not want to lower costs if it means that the poor receive less care or the "health of the nation" is lowered.[58] They do not want to lower costs if it means limiting their choice of physician or access to the technological advances in medicine or having to pay deductibles or having to give up the right to sue for malpractice.[59] The public may not be willing to accept new measures that reduce overall health costs only by altering the way health care is delivered and paid for. Educating the public to realize that they are as much a part of the problem as are the hospitals and doctors is a necessity.

Policy debates on health care in the United States are based on the assumption that everyone is entitled to the best care available regardless of one's ability to pay or whether the patient's illness is somewhat self-induced. The first of these assumptions should not be changed. In fact, a majority of Americans believe the health care system is in crisis because most Americans are getting worse care than they themselves are receiving.[60]

Perhaps the latter assumption should be reexamined. Is it reasonable that an individual who is an alcoholic and refuses to quit, or is a heavy smoker and refuses to stop, should have the same right to unlimited health care as the nonalcoholic or nonsmoker? Current policy is that they not only do but also the theory behind the "group plan" is that their increased risk of disease and the subsequent cost should be borne by everyone else. It has been estimated that the direct health costs of smoking and alcohol abuse comprise 20 percent of the health care expenditures in the U.S.[61] Some employers, because of the increased health costs, are beginning to refuse to employ smokers unless they quit. Perhaps insurance companies ought to offer better health insurance rates to low risk individuals as they do with life insurance.

Comments

At some time the American public will have to face some hard choices. When the drive to reduce costs begins to decrease that quality of health care, the relatively equal access to health care that Medicare and Medicaid has provided, or the continued advances in the biomedical sciences that have allowed the development of new dramatic headline-grabbing therapies, the country will have to ask itself how much is too much to pay for our system of health care. We will have to answer the question of whether 10 percent or 8 percent or 12 percent of the GNP is too much to pay for the health care system that has evolved at that point.

In a very few years, the American health system has dramatically changed. In the past, as George Bernard Shaw described in *The Doctor's Dilemma*, physicians have been accused of performing tests and procedures for their own financial gain. Now with prospective reimbursement and prepaid practices, physicians may be accused of not doing tests and procedures so as to make more money. The best defense against this charge is to provide a high quality of care and to speak out whenever that care is compromised by financial considerations. As one author said, "The fact that good care can be inexpensive implies neither that good care is always or usually inexpensive nor that inexpensive care is always or usually good."[62]

The question everyone is trying to answer is how do we lower the cost of medical care in this country. The question no one has answered yet (and only few have asked) is which system (or combination of systems) provides the best possible care for the most number of people at the price society is willing to pay. The answer may require enormous changes in the current health care system. However, the current system, which has worked well in the past, may be able to adjust to provide in a cost-conscious fashion the quality of care that Americans have come to expect.

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Inside Med-Chi

The Auxiliary to Med-Chi—Growth and Expansion

I pledge my support to the Auxiliary to the Medical and Chirurgical Faculty of the State of Maryland. I shall do my best to protect its reputation, enhance its achievements, and always sustain its high ideals.

For 36 years our Auxiliary of volunteers has been a loyal and supportive component of Med-Chi, adhering to the pledge taken at each state meeting and always searching for new avenues to express that pledge. The three levels of the Auxiliary Federation—county, state, and national—have progressed over the years and now are working more and more as a team. Programs such as Health Careers, Health Projects, AMA-ERF (Education and Research Foundation), Legislation, Medical Family Assistance, the Southern Medical Association, and countless promotional and fund-raising endeavors on the county level have demonstrated the value of this organization.

Our State Board is composed of eight officers, twenty-nine chairpersons and co-chairworkers plus twelve county component presidents. Our purpose is organizing and communicating many areas related to our medical interests. Ching Barretto (Mrs. Albert, Harford County) heads our health projects, including the Lady Equitable Race for which many of us train all winter. Elizabeth Linhardt (Mrs. Elmer, Anne Arundel County) has been our leader for ERF with results that place Maryland in the National winners circle year after year. Pat Bahr (Mrs. Raymond, Howard County) heads the Health Careers Day; Mary Skipton (Mrs. R. Kennedy, Prince George's County) presents our legislation, and Nancy Howell (Mrs. Daniel, Charles County) represents us at Southern Medical Association. Helen Boyer (Mrs. M. McKendree, Montgomery County) is the Chairman of MMPAC and our Parliamentarian. These are but a few of the volunteers who bring meaning to our pledge.

Our Health Projects' emphasis is on problems with Alcohol Abuse as reflected in our programs on the Fetal Alcohol Syndrome, Adolescent Nutrition, Adolescent Pregnancy, Legislation on Drunk Driving, plus specific county campaigns. The impact of these issues is felt throughout the counties and the state, and it is appropriate that the Auxiliary address these problems. As a result of our continued emphasis on health programs our Auxiliary is growing and expanding throughout the federation.

Our membership communicates an awareness of medical needs and is frequently called on to endorse worthwhile programs throughout the state. All activities are undertaken with prior discussion at the county or state level with the appropriate medical society, and we endeavor to work with them on all our projects.

State membership has grown through county expansion. The dual-billing procedure automatically brought new members and many adjustments for our State Treasurer, Vicky Kretkowski (Mrs. Ronald, Prince George's County). This increase has been retained, and our goal for '85–'86 is continued growth, not only of the general membership, chaired by Kathy Karpers, President-Elect (Mrs. Bernard, Baltimore City) but also in groups such as Members-at-Large and our Resident Physician and Medical Student Spouses. Our Members-at-Large Chairman, Madrian Snyder (Mrs. Joseph, Montgomery County) is meeting with this large group, helping them form their goals. A series of meetings have been held with the Members-at-Large in Frederick County with national, state, and county members available for questions and discussions.

Margie Warres (Mrs. H. Leonard, Baltimore City), chairman of our Resident and Student Spouse group achieved excellent results from long hours of contacting, supporting, and, in general, being available to this group of potential auxilians. Our next area of concern will be the older, retired, and widowed members.

Not only is our State organization reaching out to Maryland medical spouses, but also we lend a helping hand and receive one in return from our neighboring states. Mary Strauss (Mrs. Albert, Washington County) is the National Board's Eastern Regional Vice President, and she communicates with states from New Hampshire to Virginia.

Our latest expansion was an "informal, friendly, non-legal 'adoption'" of two Delaware counties for mutual support and an exchange of ideas. The two county presidents, Nanci Newcomb of Newcastle and Bunny Miller of Sussex, attended our fall House of Delegates Meeting in Aberdeen, Maryland, and were duly adopted. This was the first state adoption by another state Auxiliary in the history of the federation.

Other multistate activities include the two-day seminar to be held in West Virginia for the Eastern Region, concentrating on the mid-Atlantic section. This mid-March meeting continues the format begun under our immediate Past-President and National Board Member, Bobbie Niklewski (Mrs. Edmund, Washington County). The first seminar centered on Child Abuse.

Our second seminar will focus on "Substance Abuse," emphasizing prenatal and postnatal effects. Maryland will present the problem of the Fetal Alcohol Syndrome (FAS); West Virginia will discuss Smoking and Lung Problems, and Virginia will highlight Drugs other than

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Alcohol. These topics will then be discussed as related to Adolescent Pregnancy. We believe this is a timely topic and one that needs wide attention. The presenting states will be hosts, and all other Eastern Regional states are invited to attend.

Med-Chi always has been supportive of the Auxiliary's needs and interests. This is demonstrated by its willingness to present a comprehensive program at the Annual Meeting directed to physicians, spouses, and families. This year's program, arranged by J.D. Drinkard MD, President-Elect of the Faculty, will focus on problems in the medical marriage as well as address the Auxiliary's Substance Abuse concerns.

The Auxiliary to Med-Chi has grown in numbers and purpose since its beginning under Kitty Christiansen (Mrs. Thomas, Prince George's County) 36 years ago. We continue to follow our pledge by offering our time to the promotion of health projects and our contributions to medical education. The Auxiliary is a positive force for support and information within the medical community.

MILDRED TAYLOR (Mrs. Charles, Howard County)
State President, Auxiliary to Med-Chi

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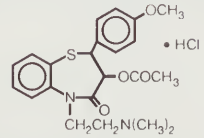
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CLINICAL PHARMACOLOGY

The therapeutic benefits achieved with CARDIZEM are believed to be related to its ability to inhibit the influx of calcium ions during membrane depolarization of cardiac and vascular smooth muscle.

Mechanisms of Action. Although precise mechanisms of its antianginal actions are still being delineated, CARDIZEM is believed to act in the following ways:

1. Angina Due to Coronary Artery Spasm: CARDIZEM has been shown to be a potent dilator of coronary arteries both epicardial and subendocardial. Spontaneous and ergonovine-induced coronary artery spasm are inhibited by CARDIZEM.
2. Exertional Angina: CARDIZEM has been shown to produce increases in exercise tolerance, probably due to its ability to reduce myocardial oxygen demand. This is accomplished via reductions in heart rate and systemic blood pressure at submaximal and maximal exercise work loads.

In animal models, diltiazem interferes with the slow inward (depolarizing) current in excitable tissue. It causes excitation-contraction uncoupling in various myocardial tissues without changes in the configuration of the action potential. Diltiazem produces relaxation of coronary vascular smooth muscle and dilation of both large and small coronary arteries at drug levels which cause little or no negative inotropic effect. The resultant increases in coronary blood flow (epicardial and subendocardial) occur in ischemic and nonischemic models and are accompanied by dose-dependent decreases in systemic blood pressure and decreases in peripheral resistance.

Hemodynamic and Electrophysiologic Effects. Like other calcium antagonists, diltiazem decreases sinoatrial and atrioventricular conduction in isolated tissues and has a negative inotropic effect in isolated preparations. In the intact animal, prolongation of the AH interval can be seen at higher doses.

In man, diltiazem prevents spontaneous and ergonovine-provoked coronary artery spasm. It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure and, in exercise tolerance studies in patients with ischemic heart disease, reduces the heart rate-blood pressure product for any given work load. Studies to date, primarily in patients with good ventricular function, have not revealed evidence of a negative inotropic effect; cardiac output, ejection fraction, and left ventricular end diastolic pressure have not been affected. There are as yet few data on the interaction of diltiazem and beta-blockers. Resting heart rate is usually unchanged or slightly reduced by diltiazem.

Intravenous diltiazem in doses of 20 mg prolongs AH conduction time and AV node functional and effective refractory periods approximately 20%. In a study involving single oral doses of 300 mg of CARDIZEM in six normal volunteers, the average maximum PR prolongation was 14% with no instances of greater than first-degree AV block. Diltiazem-associated prolongation of the AH interval is not more pronounced in patients with first-degree heart block. In patients with sick sinus syndrome, diltiazem significantly prolongs sinus cycle length (up to 50% in some cases).

Chronic oral administration of CARDIZEM in doses of up to 240 mg/day has resulted in small increases in PR interval, but has not usually produced abnormal prolongation. There were, however, three instances of second-degree AV block and one instance of third-degree AV block in a group of 959 chronically treated patients.

Pharmacokinetics and Metabolism. Diltiazem is absorbed from the tablet formulation to about 80% of a reference capsule and is subject to an extensive first-pass effect, giving an absolute bioavailability (compared to intravenous dosing) of about 40%. CARDIZEM undergoes extensive hepatic metabolism in which 2% to 4% of the unchanged drug appears in the urine. In vitro binding studies show CARDIZEM is 70% to 80% bound to plasma proteins. Competitive ligand binding studies have also shown CARDIZEM binding is not altered by therapeutic concentrations of digoxin, hydrochlorothiazide, phenylbutazone, propranolol, salicylic acid, or warfarin. Single oral doses of 30 to 120 mg of CARDIZEM result in detectable plasma levels within 30 to 60 minutes and peak plasma levels two to three hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3.5 hours. Desacetyl diltiazem is also present in the plasma at levels of 10% to 20% of the parent drug and is 25% to 50% as potent a coronary vasodilator as diltiazem. Therapeutic blood levels of CARDIZEM appear to be in the range of 50 to 200 ng/ml. There is a departure from dose-linearity when single doses above 60 mg are given; a 120-mg dose gave blood levels three times that of the 60-mg dose. There is no information about the effect of renal or hepatic impairment on excretion or metabolism of diltiazem.

INDICATIONS AND USAGE

1. **Angina Pectoris Due to Coronary Artery Spasm.** CARDIZEM is indicated in the treatment of angina pectoris due to coronary artery spasm. CARDIZEM has been shown effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (resting angina with ST-segment elevation occurring during attacks).
2. **Chronic Stable Angina (Classic Effort-Associated Angina).** CARDIZEM is indicated in the management of chronic stable angina. CARDIZEM has been effective in controlled trials in reducing angina frequency and increasing exercise tolerance.

There are no controlled studies of the effectiveness of the concomitant use of diltiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities.

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

1. **Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
2. **Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
3. **Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
4. **Acute Hepatic Injury.** In rare instances, patients receiving CARDIZEM have exhibited reversible acute hepatic injury as evidenced by moderate to extreme elevations of liver enzymes. (See PRECAUTIONS and ADVERSE REACTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS).

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vitro bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outweigh its potential risks in this situation.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences, as well as their frequency of presentation, are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%), AV block (1.1%). In addition, the following events were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrence.

Cardiovascular:	Flushing, arrhythmia, hypotension, bradycardia, palpitations, congestive heart failure, syncope.
Nervous System:	Paresthesia, nervousness, somnolence, tremor, insomnia, hallucinations, and amnesia.
Gastrointestinal:	Constipation, dyspepsia, diarrhea, vomiting, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH.
Dermatologic:	Pruritus, petechiae, urticaria, photosensitivity.
Other:	Polyuria, nocturia.

The following additional experiences have been noted:

A patient with Prinzmetal's angina experiencing episodes of vasospastic angina developed periods of transient asymptomatic asystole approximately five hours after receiving a single 60-mg dose of CARDIZEM.

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: erythema multiforme; leukopenia; and extreme elevations of alkaline phosphatase, SGOT, SGPT, LDH, and CPK. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

OVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with oral diltiazem has been limited. Single oral doses of 300 mg of CARDIZEM have been well tolerated by healthy volunteers. In the event of overdosage or exaggerated response, appropriate supportive measures should be employed in addition to gastric lavage. The following measures may be considered:

Bradycardia	Administer atropine (0.60 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.
High-Degree AV Block	Treat as for bradycardia above. Fixed high-degree AV block should be treated with cardiac pacing.
Cardiac Failure	Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics.
Hypotension	Vasopressors (eg, dopamine or levarterenol bitartrate).

Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating physician.

The oral/LD_{50}'s in mice and rats range from 415 to 740 mg/kg and from 560 to 810 mg/kg, respectively. The intravenous LD_{50}'s in these species were 60 and 38 mg/kg, respectively. The oral LD_{50} in dogs is considered to be in excess of 50 mg/kg, while lethality was seen in monkeys at 360 mg/kg. The toxic dose in man is not known, but blood levels in excess of 800 ng/ml have not been associated with toxicity.

DOSAGE AND ADMINISTRATION

Exertional Angina Pectoris Due to Atherosclerotic Coronary Artery Disease or Angina Pectoris at Rest Due to Coronary Artery Spasm. Dosage must be adjusted to each patient's needs. Starting with 30 mg four times daily, before meals and at bedtime, dosage should be increased gradually (given in divided doses three or four times daily) at one- to two-day intervals until optimum response is obtained. Although individual patients may respond to any dosage level, the average optimum dosage range appears to be 180 to 240 mg/day. There are no available data concerning dosage requirements in patients with impaired renal or hepatic function. If the drug must be used in such patients, titration should be carried out with particular caution.

Concomitant Use With Other Antianginal Agents:

1. **Sublingual NTG** may be taken as required to abort acute anginal attacks during CARDIZEM therapy.
2. **Prophylactic Nitrate Therapy**—CARDIZEM may be safely coadministered with short- and long-acting nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.
3. **Beta-blockers.** (See WARNINGS and PRECAUTIONS.)

HOW SUPPLIED

Cardizem 30-mg tablets are supplied in bottles of 100 (NDC 0088-1771-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1771-49). Each green tablet is engraved with MARION on one side and 1771 engraved on the other. CARDIZEM 60-mg scored tablets are supplied in bottles of 100 (NDC 0088-1772-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1772-49). Each yellow tablet is engraved with MARION on one side and 1772 on the other.

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Discipline Commission Action

In the Matter of
Nathaniel Aikins-Afful MD
Before the
Commission on
Medical Discipline
of Maryland

Based upon information coming to its attention, the Commission on Medical Discipline of Maryland (the Commission) conducted an investigation and subsequently determined to charge Nathaniel Aikins-Afful MD (Respondent) with violation of §14-504(6) of the Maryland Medical Practice Act, (the Act) Health Occupations Article, Annotated Code of Maryland, which provides:

> Subject to the hearing provisions of §14-505 of this subtitle, the Commissions on the affirmative vote of a majority of its full authorized membership, may reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee:
>
> • • •
>
> (6) Is convicted of or pleads guilty or nolo contendere with respect to a crime involving moral turpitude whether or not any appeal or other proceeding is pending to have the conviction or plea set aside;
>
> • • •

Findings of Fact

Based upon the information in its files, and otherwise made known to it, the Commission finds:

1. That Respondent, is a physician licensed and practicing in Maryland both currently and at all times material to the allegations relating to the above matter;

2. That on February 3, 1983, Respondent pled guilty to a violation of Article 27 §230C of the Annotated Code of Maryland (Medicaid Fraud) in the Circuit Court for Baltimore City, Criminal Information Number 28236303;

3. That the charge to which Respondent pled guilty was based upon his obtaining reimbursement from the Maryland Medical Assistance Program (Medicaid) for physician services received by patients at Provident Hospital. Respondent was the attending physician in 29 deliveries by obstetric resident physicians at Provident Hospital. Although Respondent was not present at the deliveries, he received reimbursement for his professional services.

5. That on April 18, 1983 Respondent received the following sentence from the Circuit Court for Baltimore City: two (2) years imprisonment, which was suspended; three years supervised probation; restitution in the amount of $12,000; a fine of $5,000; and 150 hours of unpaid community service.

Conclusions of Law

Based upon the foregoing Findings of Facts, the Commission on Medical Discipline, by unanimous vote of a quorum of its members, concludes as a matter of law that Respondent violated §14-504(6) of the Maryland Medical Practice Act, Health Occupations Article, Annotated Code of Maryland, and finds Respondent GUILTY of that charge.

Order

Based upon the foregoing Findings of Fact and Conclusions of Law, it is this 2nd day of October 1984, by unanimous vote of a quorum of the members of the Commission on Medical Discipline,

ORDERED that the license of Respondent, Nathaniel Aikins-Afful MD, an individual licensed to practice medicine in the State of Maryland, is hereby REVOKED; and be it further ORDERED that the revocation of Respondent's license shall be immediately STAYED and Respondent placed on PROBATION subject to the following terms and conditions:

1. That Respondent shall arrange for his probation officer to file written reports with the Commission. Each report shall verify that the Respondent is complying with all of the terms and conditions of his criminal probation, including the payment of any fine, completion of restitution and performance of community service. The first report shall be filed by the probation officer thirty days from the effective date of this Order and shall, thereafter, continue to be filed on a quarterly basis during the period of probation pursuant to the Order. If the Respondent shall be discharged from his criminal probation prior to the termination of his probation pursuant to this Order, Respondent shall arrange for his probation officer to give immediate written notice of such discharge to the Commission;

2. That Respondent shall not engage in activities of the type that led to his criminal conviction;

3. That Respondent shall not violate any other provisions of the Maryland Medical Practice Act, Health Occupations Article §14-101 *et seq.*, Annotated Code of Maryland; and

4. That Respondent shall practice fully in accordance with those standards expected of a competent practitioner of medicine in the State of Maryland; and be it further

ORDERED that three (3) years from the date of this Order the Commission will entertain a petition for termination of Respondent's probationary status and for restoration of his license to practice medicine without condition or restriction, upon Respondent's demonstrating to the satisfaction of the Commission that he has compiled with the terms and conditions of his probation. If the Commission determines that he has not complied with the terms and conditions of his probation, the Commission may modify one or more of the conditions of his probation; and be it further

ORDERED that if Respondent violates any of the

On instruction of the Council of the Medical and Chirurgical Faculty of the State of Maryland, "Findings of Fact, Conclusions of Law, and Order" will be published in the Maryland Medical Journal.

foregoing conditions of probation, the Commission, after notification, a hearing, and determination of violation, may impose any disciplinary sanctions it deems appropriate.

HILARY T. O'HERLIHY MD, **Chairman**
Commission on Medical Discipline of Maryland

Consent

By this Consent, I hereby admit the truth of the above Findings of Fact and accept and submit to the foregoing Order and its conditions. I have read and acknowledge the validity of the Order as if made after a hearing in which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my behalf, and to all other substantive and procedural protections provided by law. I also recognize that I am waiving my right to appeal any adverse ruling of the Commission that might have followed any such hearing. By this Consent, I understand that I am waiving all such rights and acknowledge that by my failure to abide by the conditions of the Order, I may suffer disciplinary action against my license to practice medicine in the State of Maryland. I sign this Consent without reservation and after conferring with counsel. I fully understand its meaning.

NATHANIEL AIKINS-AFFUL MD

Re: William H. Choate MD

Notice is hereby given by the Commission on Medical Discipline that the probationary status of the above reference physician is hereby terminated as of March 11, 1984. Dr. Choate's license is restored in full and is free of any conditions or restrictions whatsoever.

KARL F. MECH MD, **Executive Secretary**
Commission on Medical Discipline
October 7, 1984

In the Matter of Dorothy Cothran MD Before the Commission on Medical Discipline of Maryland

Order Regarding Emergency Suspension of Medical License

On August 7, 1984, based on information received from the Division of Drug Control (the DDC) of the Maryland Department of Health and Mental Hygiene and further investigation by the Committee on Drugs and Peer Review Committee of the Medical and Chirurgical Faculty of the State of Maryland (Med-Chi) regarding the medical practice of Dorothy Cothran MD (the Respondent), the Commission on Medical Discipline of Maryland (the Commission) ordered that Respondent's medical license be summarily suspended, pursuant to Article 41 §250A(c) of the Annotated Code of Maryland, to the extent that it permitted her to prescribe controlled dangerous substances (the 1984 Order).

By letter dated August 9, 1984, Respondent requested a hearing before the Commission on the emergency suspension of her medical license.

Findings of Fact

1. That at all times relevant to this Order, Respondent was licensed to practice medicine in Maryland.
2. That Respondent specializes in family practice medicine in Montgomery County, Maryland.
3. That in October and November 1983 and April 1984, DDC drug inspectors conducted a controlled dangerous substances audit of prescriptions written by Respondent and filled at various pharmacies in Montgomery County, Maryland.
4. That based on this audit, the drug inspectors discovered that Respondent had written prescriptions for unusually large quantities of controlled dangerous substances for a number of her patients.
5. That because of Respondent's unusual prescription pattern for controlled dangerous substances, DDC forwarded its findings to Stephen A. Hirsch MD, Chairman of Med-Chi's Committee on Drugs.
6. That on March 13, 1984, members of the Committee on Drugs met with Respondent to determine why such a large proportion of her patients received prescriptions for controlled dangerous substances.
7. That as a result of the March 13, 1984 meeting, all of the members of the Committee on Drugs were "distressed" by Respondent's "attitude and philosophy toward prescribing and the practice of medicine."
8. That the Committee on Drugs further concluded that Respondent failed to document appropriately the medical indications for the controlled dangerous substances she prescribed for a number of her patients.
9. That the Committee on Drugs decided to refer

Respondent's case to the Med-Chi Peer Review Committee for a thorough review of Respondent's entire medical practice.

10. That the Peer Review Committee subsequently requested Liebe Sokol Diamond MD and Edward J. Richards MD to conduct an on-site peer review of Respondent's medical practice.

11. That on May 30, 1984, Drs. Diamond and Richards visited Respondent's office in Rockville, Maryland to conduct an on-site peer review of her medical practice. Based on their interview with Respondent and the review of patient records, they each prepared a written report.

12. That based on the entire record, including the medical charts of Patient's A, B, C, D, E, F, G, H, I, J, K, and L,* the Commission finds that there is probable cause to believe that Respondent's drug management of these patients was inappropriate and below the standard of a reasonably competent family practitioner in Maryland.

13. That the Commission concurs with the Peer Review Committee's conclusion that Respondent's "attitude toward prescribing was lax, either from a lack of knowledge of drugs or from a faulty attitude."

Conclusion of Law

By a unanimous vote of the members of the Commission hearing this case, the Commission concludes as a matter of law:

1. That the Commission has probable cause to believe that Respondent violated §14-504(4) of the Health Occupations Article of the Annotated Code of Maryland which provides that the Commission may discipline a physician if she "[i]s professionally, or physically, or mentally incompetent."

2. That the Commission's 1984 Order, issued pursuant to Article 41, §250A(c) of the Annotated Code of Maryland, was justified because Respondent's continued ability to prescribe controlled dangerous substances would pose an imminent and grave danger to her patients and the public health, safety, and welfare and that that situation imperatively requires that the Commission continue the emergency suspension prior to its filing and considering charges against Respondent's license to practice medicine.

Order

Upon the foregoing Findings of Fact and Conclusions of Law, it is this 9th day of October 1984, by a unanimous vote of the members of the Commission considering this case

ORDERED that the Commission's 1984 Order summarily suspending Respondent's medical license to the extent that it permits her to prescribe controlled dangerous substances is hereby AFFIRMED and CONTINUED; and be it further

ORDERED that Respondent shall continue to cease and desist prescribing any and all controlled dangerous substances.

HILARY T. O'HERLIHY MD, **Chairman**
Commission on Medical Discipline of Maryland

Re: Edward E. Holt MD

Notice is hereby given by the Commission on Medical Discipline that the probationary status of the above referenced physician is hereby terminated as of this date. Dr. Holt's license is restored in full and is free of any conditions or restrictions whatsoever.

KARL F. MECH **MD**
Executive Secretary
October 3, 1984

Re: Ernest Katz MD

Notice is hereby given by the Commission on Medical Discipline of Maryland that the probationary status of the above referenced physician is hereby terminated as of this date. Dr. Katz's license is restored in full and is free of any conditions or restrictions whatsoever.

KARL F. MECH **MD**
Executive Secretary
October 3, 1984

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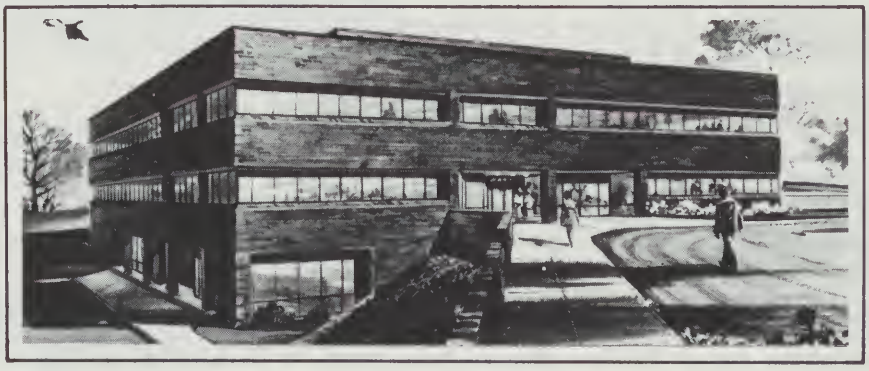
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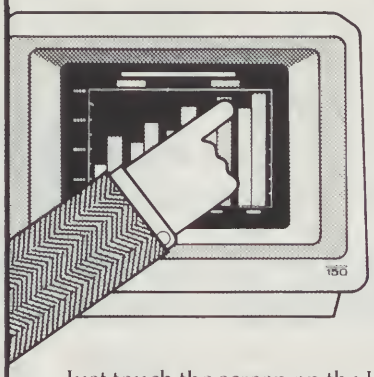
Medical Miscellany

The American Society of Handicapped Physicians, headquartered at 137 Main St., Grambling, LA, with its 800 members in 45 states, Canada, Cuba, India, Greece, England, and Thailand held its third annual conference in St. Louis, MO, last May. Newly elected officers include:

Stanley Wainapel MD, Boston, MA—President
Terry Winkler, Bastrop, LA—Chairman of the Board of Directors
Russell Pavich MD, Eunice, LA—President-Elect
Suzanne Stelmach MD, Jacksonville, NC—Vice President
Mary Lewis CNM, MS, Grambling, LA—Executive Vice President
Merly Aliberti EMT, New York, NY—Recording Secretary

ASHP was founded in April 1981 by a nationally recognized physician who is blind, Spencer B. Lewis, of Grambling, LA. This nonprofit organization offers assistance through support, advocacy, rehabilitation, education, and employment to physically disabled or handicapped persons who have chosen a medical career.

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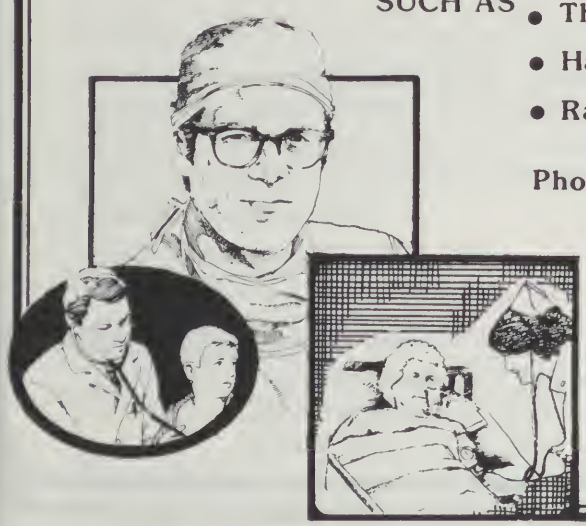
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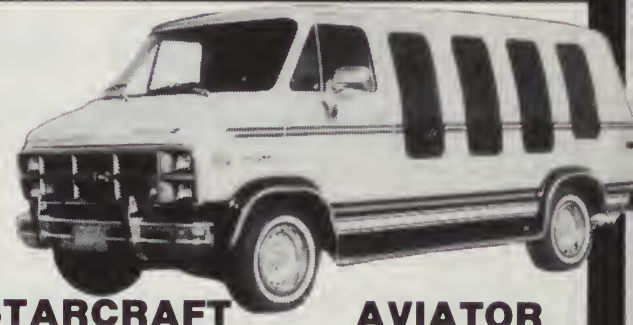
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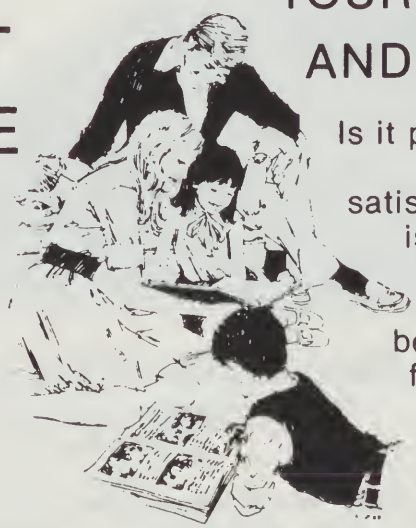
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Members in the News

Sergio Alvarez MD, has been named Chief of Surgery at North Arundel Hospital. Associated with North Arundel Hospital since 1966, Dr. Alvarez graduated from the University of Mexico's Medical School and completed his surgical training at St. Joseph Hospital and St. Agnes Hospital. He is a fellow of the American College of Surgery.

• • •

Franklin L. Angell MD, Severna Park, head of the radiology department at Baltimore's Mercy Hospital, has been appointed to the association development committee of the Maryland Hospital Association. Dr. Angell becomes the first physician to serve on the statewide panel of hospital executives and trustees, which is the association's main policy advisor for membership and long-range planning issues. The MHA is a nonprofit, nongovernment group organized nearly 15 years ago as a vehicle for cooperation among the state's 64 community acute care and special hospitals.

"We are particularly pleased to add a physician of national stature such as Dr. Angell to the committee that helps to plan the association's future," said MHA Board Chairman E. Scott Moore in announcing the appointment.

Long active with the American College of Radiology, Dr. Angell has been Speaker of its Council since 1983 and has served on numerous committees and commissions for the national organization of radiologists. He is a former president of Mercy's medical staff and has chaired its medical executive committee. He has lectured and written widely on both management and clinical topics in health care.

• • •

B. Stanley Cohen MD, chief of rehabilitation medicine at Sinai Hospital, has been elected chairman of the American Board of Physical Medicine and Rehabilitation, the national certifying body for specialists in those fields. Established in 1947 with headquarters in Rochester, Minnesota, the Board has certified approximately 2,000 physiatrists since then. Dr. Cohen represents the Board on the Residency Review Committee and the American Board of Medical Specialties.

• • •

David M. Cook MD, chief of the section of neurological surgery at Franklin Square Hospital, has been reelected president of the medical staff at the hospital. He is currently serving as an instructor at the University of Maryland Hospital in the Department of Neurosurgery.

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Elliott R. Fishel MD was installed as President of the Baltimore City Medical Society at its annual meeting in December 1984. Dr. Fishel, a native Baltimorean, received his MD degree from the Johns Hopkins University School of Medicine in 1950 and served an internship and residencies in surgery at Hopkins and at the Veterans' Administration Hospital at Perry Point. Following training, he entered private practice in Baltimore in 1956 and became a fellow in the American College of Surgeons and in the American Occupational Medical Association. Dr. Fishel is currently medical codirector of the Central Medical Center in Baltimore.

Other officers installed at the meeting were **Gary L. Rosenberg** MD, President-elect; **Jose M. Yosuico** MD, Vice President; **Hiroshi Nakazawa** MD, Secretary; and **Paul Bormel** MD, Treasurer.

• • •

The American College of Physicians (ACP) announced that **Philip Howard Konits** MD, Baltimore, has been elected to Fellowship in the 60,000-member national medical specialty society. Dr. Konits, a specialist in medical oncology, will be honored during the Convocation ceremony at the College's Annual Session in Washington, DC, March 28–31, 1985.

Dr. Konits is one of 16,000 physicians honored with Fellowship in the College—about 300 have been elected this year. A 1975 graduate of the University of Rochester, Dr. Konits has been a resident of Baltimore for seven years and is on the staff of the Lutheran Hospital, Bon Secours Hospital, North Arundel Hospital, South Baltimore General Hospital, and St. Agnes Hospital.

• • •

Richard D. Richards MD, ophthalmologist from Baltimore, current President of the Southern Medical Association, presided at its 78th Annual Scientific Assembly held at the Rivergate, New Orleans, in November 1984.

Dr. Richards is Professor and Chairman of the Department of Ophthalmology at the University of Maryland School of Medicine.

A graduate of the University of Michigan, Dr. Richards received his Doctorate of Medicine from the University of Michigan and a Master of Science degree in ophthalmology from the State University of Iowa. He served in the United States Army Medical Corps and was Assistant Professor of Ophthalmology at the State University of Iowa before coming to Baltimore.

The Southern Medical Association, a voluntary association of 43,000 physicians, was founded over 75 years ago with the sole purpose of fostering scientific medicine. Although it is independent of other medical societies, it works closely with them. Its territory consists of 16 southern states and the District of Columbia.

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William A. Rinn MD, Towson, received a John Carroll award from Georgetown University in October 1984. This award is given to alumni of the University, selected by the Alumni Association, for special distinction. Recipients are chosen on the basis of career ac-

complishment, involvement in public service work, dedication to University principles, and volunteer service to Georgetown.

Dr. Rinn, a 1948 graduate of Georgetown's School of Medicine, is psychiatrist at the Baltimore County Detention Center and consultant psychiatrist, St. Joseph Hospital, Towson. He served as director, Psychiatric Service, at Bon Secours Hospital from 1965 to 1979.

• • •

Henry Scagliola MD has been appointed medical director of the new Fallston General Occupational Health Center at the Fallston Professional Building, 1916 Belair Road. Dr. Scagliola served an internship at Tripler Army Hospital in Honolulu, Hawaii, and a residency in general preventive medicine at Walter Reed Army Institute of Research.

• • •

J. Andrew Sumner MD, assistant chairman of the department of emergency medicine at Franklin Square Hospital, has been elected president of the Maryland Chapter of the American College of Emergency Physicians. He is a graduate of Tulane University Medical School. Dr. Sumner completed a residency in Emergency Medicine at Georgetown Medical University.

• • •

Raymond K. Wright, Jr. MD has been named head of the gynecology section of Fallston General Hospital. Dr. Wright received a bacheolor's degree in science from Bridgewater College in Virginia, and a medical degree from the University of Maryland School of Medicine. After completing his medical internship at Sinai Hospital, Dr. Wright served a residency in obstetrics and gynecology at Franklin Square Hospital.



American College of Surgeons
Maryland Chapter Meeting
September 1984, Baltimore

From left: B. Martin Middleton MD, State Governor; John Knud-Hansen MD, President, Maryland Chapter, ACS; James Sammons MD, Executive Vice-President AMA; Gilbert Armiger MD, Program Chairman; Paul Bormel MD, Past President, Maryland Chapter, ACS; Stephen Padussis MD, Maryland Delegate to the AMA.

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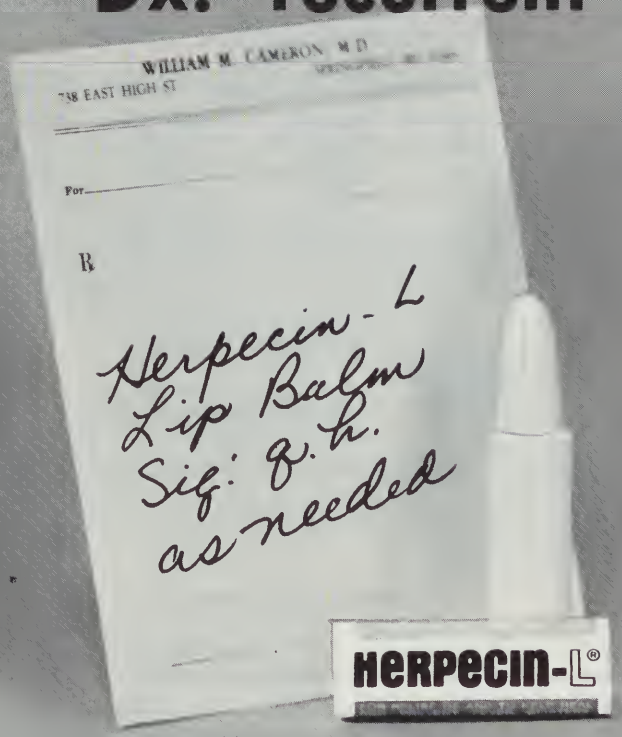
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Contest Rules

1. Photographs may be submitted in two categories—BLACK and WHITE or COLOR.
2. Limit: three entries per person.
3. Entries must have name, address, and telephone number attached to the back of each photograph.
4. PRINTS only, no smaller than 8 × 10 or larger than 11 × 14, will be accepted. If your favorite shot is a slide, you must have a print made within these size ranges to enter in the contest.
5. Entries may be mailed or brought to the Faculty Office, 1211 Cathedral Street, Baltimore, Maryland 21201 by the close of the business day on March 27, 1985.
6. Entries MUST be matted or dry mounted. No framed photographs will be accepted.
7. Photographs entered in the contest will be on display at the Annual Meeting in April 1985.
8. Winners will be announced at the Annual Meeting of the Medical and Chirurgical Faculty, April 25 thru 27, 1985.
9. Photographs will NOT be mailed back. Photographs may be claimed at the exhibit area at the close of the Annual Meeting on Saturday, April 27 at noon or at the Faculty Building thereafter.
10. The Faculty does not guarantee against loss or damage of any kind to the photographs submitted to the contest.
11. Prizes will be awarded to the FIRST and SECOND place winners. Additional information about the prizes will be published in the JOURNAL.

Doctors Take Note

Taylor Manor Hospital CME Lectures

All lectures at 3 p.m. in the Psychiatric Center at Taylor Manor Hospital, Ellicott City, MD unless otherwise indicated. Info: Taylor Manor Hospital, College Ave., Ellicott City, MD 21043 (301-465-3322)

Feb 20 The Young Chronic Schizophrenic

Mar 20 Psychopathology of Young Women (Psychosomatic Aspects)

• • •

The Johns Hopkins Medical Institution

All courses at the Turner Auditorium Building unless otherwise indicated. Sponsored Continued Education Activities for 1984–85. Info: Office of Continuing Education, 720 Rutland Ave., Turner Auditorium, Baltimore, MD 21205 (301-955-5880).

Feb 28–Mar 3 Computed Body Tomography 1985–The Cutting Edge, sponsored by The Johns Hopkins University School of Medicine, held at Fort Lauderdale, FL. Fees: $250 ($175, residents and fellows with letter); 21 AMA Cat I credits.

Mar 2 Clinical Aspects of Aging: Aging in Blacks. Cosponsor: Morgan State University and Monumental Medical Society. Info: A. Kearney (301-955-6046)

Mar 14–15 Quantitative Imaging of the Neuroreceptors in the Human Brain. Fee: $200; Cat I AMA credits, Psychology CEUs. Info: A. Kearney Program Coordinator (301-955-6046)

Mar 23–24 Hemodynamic Monitoring/Patient Care and Pulmonary Artery Catheterization, sponsored by the Department of Anesthesiology and Critical Care Medicine. Fee: $350; 12.5 AMA Cat I credits. Info: P. Nulle (301-955-6046).

Apr 10–11 Topics in Ambulatory Medicine, at the Hyatt Regency Baltimore. Fee: $295, $150 for residents and fellows; 17 AMA Cat I credits. Info: P. Nulle (301-955-6046).

Apr 11–12 Eleventh Annual Symposium on Diagnosis and Treatment of Neoplastic Disorders: Medical, Surgical & Radiotherapeutic Aspects, at the Oncology Center. Fee: $225 (includes social activities); 16 AMA Cat I credits. Info: Prog. Coord. (301-955-6046).

Apr 16–17 Asbestos: The Workplace, Buildings and Schools—Risk Assessment and Management. Fee: $300; 16 AMA Cat I credits; continuing education units; ABIH certification. Info: C. Kearney (301-955-5880).

Apr 20 Current Concepts in Thyroid Disease. Fee: $90; 9 AMA Cat I credits. Info: D. Heydinger (301-955-6046)

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The Department of Radiology and Radiological Science, offers several courses in abdominal and obstetrical ultrasound: courses scheduled Jan 14 to Dec 6, 1985. Info: Joan Mosmiller, Department of Radiology (301-955-8450)

Basic Practicum—Mar 11–15; June 3–7; Aug 5–9; Sep 23–27. Fee: $460; 40 AMA Cat I credits

Advanced Practicum—May 13–17; Dec 2–6. Fee $460; 40 AMA Cat I credits

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Advanced Obstetrics and Gynecology course designed for obstetricians who have been using real time ultrasound. Apr 15–17; Nov 18–20. Fee: $325; 24 AMA Cat I credits.

Diagnostic Ultrasound in Obstetrics and Gynecology course given annually attracts world's leading experts in the field of obstetrical and gynecology ultrasound. Sep 12–13, 1985; 16 AMA Cat I credits.

The Johns Hopkins Medical Grand Rounds: accredited audiovisual subscription program for the practicing physician. 40 AMA Cat I credits/year. Write to the Johns Hopkins University School of Medicine, Office of Continuing Education, 720 Rutland Ave., Baltimore, MD 21205 (301-955-3988)

Clinical Cytopathology for Pathologists, 1985 Postgraduate Institute: March to May 1985, Home Study Course A; **May 6–17,** In-Residence Course B at the Johns Hopkins Medical Institution, Baltimore. Designed solely for pathologists who are Certified (or qualified for certification) by the American Board of Pathology or its international equivalent, this is an intensive refresher in all aspects of the field of Clinical Cytopathology. Topics are covered in lectures, in small informal conferences, and over the microscope. Self-instructional material is available. Loan set of slides with texts (Course A) will be sent to each participant within the U.S. and Canada for home study during March and April before Course B in Baltimore. Special arrangements to study Course A must be made by participants outside the U.S. and Canada. 152 AMA Cat I credits. *The entire course given in English.*

Completed preregistration must be accomplished before **April 5, 1985,** unless by special arrangement. Info: John K. Frost, MD, 604 Pathology, Bldg., The Johns Hopkins Hospital, Baltimore, MD 21205, USA

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University of Maryland School of Medicine

CME Courses: For each course additional information may be obtained by contacting Program of Continuing Education, University of Maryland School of Medicine, Room 300, MSTF, 10 South Pine St., Baltimore, MD 21201 (301-528-3956)

Feb 7–May 14 Advanced Immunology. 15 AMA Cat I credits. Info: 301-528-7110

Feb 21–Mar 28 Selected Topics in Family Practice; Spring Series, Baltimore. Fee $100, 15 AMA Cat I credits

Mar 24–29 Fifth Annual Postgraduate Course in Neurological Disorders: Stroke and Tumors, Paradise Island, The Bahamas. Fee: $425; 25 AMA Cat I credits.

Apr 12–13 First Annual University of Maryland Contact Lens Symposium. Columbia Inn. Fee: $165; 11.5 AMA Cat I credits.

May 3–4 Contemporary Issues in the Diagnosis and Management of Chronic Congestive Heart Failure. Baltimore. Fee: $170; 10 AMA Cat I credits.

Oct thru May—Visiting Practitioner Preceptorship Program. CME experience on full-time clinical basis in choice of discipline; 5 days to 6 weeks. Hour-for-hour AMA Cat I credit.

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Miscellaneous Meetings

Feb 20–24 Third Annual Winter Continuing Medical Education Festival, sponsored by Geisinger Clinic. Pocono Hershey Resort, White Haven. Fee: $115 for physicians, $95 for students; 25 Cat I credits and workshops. Info: S. Hanley, Continuing Education Program Registrar, Geisinger Medical Center, Danville, PA 17822 (717-271-6692)

Feb 20–22 Thromboembolic and Atherosclerotic Disease—An Update on Pathogenesis, Prevention, and Treatment, American College of Cardiology's Learning Center, Bethesda. Fee; $375, for College members; $425 for nonmembers. 17.5 ACCME Cat I credits. Info: ACC, Learning Center Registrar, 9111 Old Georgetown Road, Bethesda, MD 20814 (301-897-5400, ext 241)

Feb 25–27 Cardiovascular Surgery; Coronary—Extending the Procedure; Valvular—Matching the Patient, Challenging Management Problems, American College of Cardiology's Learning Center, Bethesda. Fee: $375 for College members; $435 for nonmembers. 17 ACCME Cat I credits. Info: ACC, Learning Center Registrar, 911 Old Georgetown Road, Bethesda, MD 20814 (301-897-5400, ext. 241)

Mar 13 Antarctica. CME topic of the American Medical Women's Association. Meeting held at the Johns Hopkins Faculty Club, Homewood Campus; cash bar at 6:30 p.m.; dinner at 7 p.m.

Apr 19–21 Emergency Medicine for the Primary Care Physician, sponsored by the Office of Continuing Medical Education, the Medical College of Virginia. Fee: $250; 16.5 instruction hours. Info: K. Martin (804-786-0494)

Apr 22–24 NIH Consensus Development Conference: Anesthesia and Sedation in the Dental Office. NIH Clinical Center, Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Info: P. Murphy, Prospect Associates, Suite 401, 2115 E. Jefferson St., Rockville, MD 20852 (301-468-6555).

Apr 25–28 Annual Meeting, The Virginia Society of Otolaryngology-Head and Neck Surgery, Tides Inn, Irvington, VA. Info: D. Strawdermann, 4205 Dover Road, Richmond VA 23221 (804-353-2721)

May 8 Disability and the Social Security Administration. CME topic of the American Medical Women's Association. Meeting held at the Johns Hopkins Faculty Club, Homewood Campus; cash bar at 6:30 p.m.; dinner at 7 p.m.

May 8–11 Annual Meeting, The Virginia Society of Ophthalmology, Boar's Head Inn, Charlottesville, VA. Cosponsored by University of Virginia Ophthalmology Dept. Info: D. Strawderman, 4205 Dover Road, Richmond, VA 23221 (804-353-2721)

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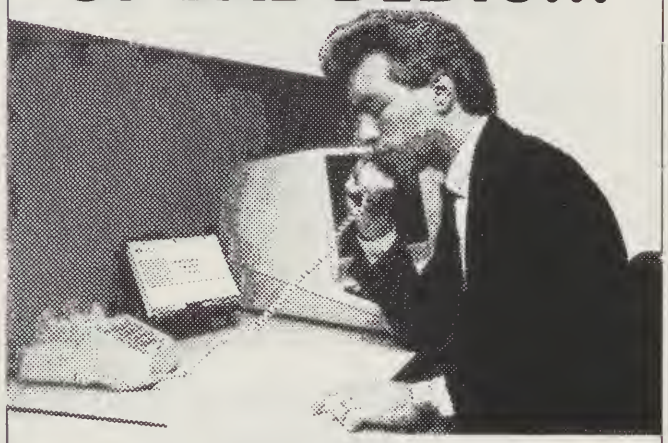
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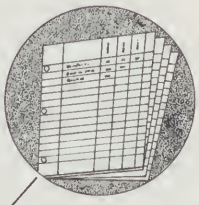
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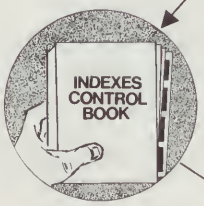
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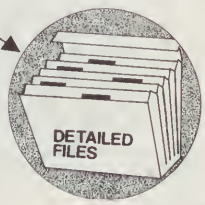
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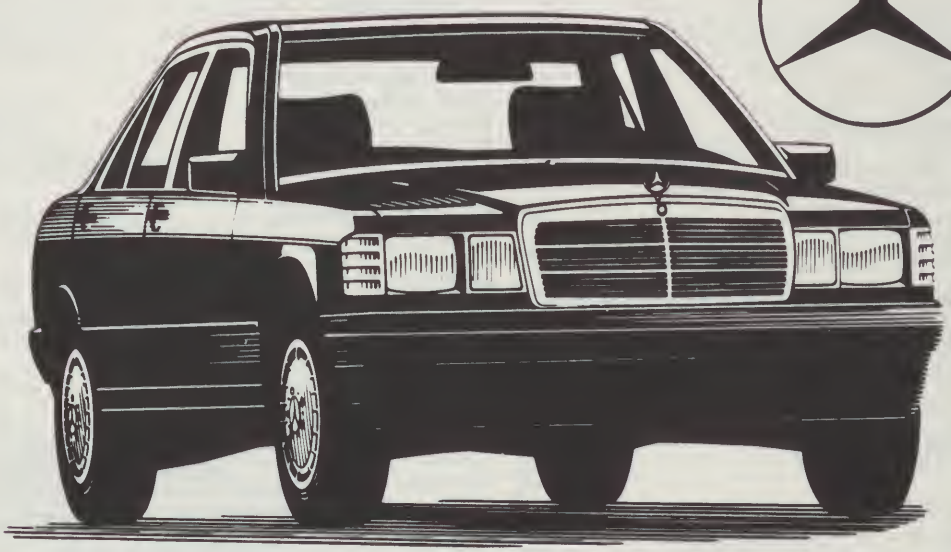
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Advertisers' Index

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American College of Physicians 127
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Associated Speech and Language Services 198
Ayerst Laboratories 137
Victor Boehm Bldg. Co. 162
Bonnie Ridge Apartments 192
Bon Secours Professional Center 118
BTR Realty, Inc. 200
Business Automation, Inc. 166
Campbell Laboratories 192
Campus Books, Inc. 187
The Carousel Hotel 144
Consultative Examinations 199
Herbert Cox Corrective Shoes 200
Curtis 1000 Information Systems 126
Diagnostic Assay Services 107
Dickinson Medical Group 198
Eastman Kodak 123
Elkridge Estates 176
Executive Billing Assoc. 188
Family Home Care 115
Family Recovery Center 198
Franklin Square Hospital 183
Freestate Management Co. 186
Gladding Leasing, Inc. 192
GMC Truck Center 188
I. Elliott Goldberg Attorney 184
Gordon and Heneson PA 185
Heron Harbour Isle 121
Hidden Brook Treatment Center 122
Hill Management Services 132
Howard County Medical Center 198
Jerry's Toyota 146
King's Grant 103
Knoll Pharmaceutical 158
Joel R. Kruh Esquire 196
Lewis Medical Instruments 189
Eli Lilly 106
Management Information System Corp. 197
Marion Laboratories 177
Maryland Army National Guard 185
Maryland Medical Laboratory 103
Maryland Office Systems 187
McGrow, Pridgeon & Co. 112
Med-Chi 190, 196, 200
Medical Mutual Liability ..... cover 2
Michaelson Motors, Inc. 184
Micro Age 117
Miller Studio 176
Motor Coach 183
Mountain Manor Treatment Center 155
MULTICOM INC. 156
National Credit Management Corp. 197
Nurses, Inc. 162
Old Court Nursing Center 184
Earl S. Oxley CPA 115, 132
Personal Organization, Inc. 200
PM Baltimore 186
Public Phone Stores 152
Roche Laboratories ..... covers 3 and 4
W. James Schiller & Co. PA 176
Schumacher & Seiler, Inc. 179
Sheraton Inner Harbor Hotel 141
Staff Builders 176
St. Agnes Hospital 199
Len Stoler Porsche/Audi 166
The Strutt Group 145
Stuart Pharmaceutical 113
Sunspace Design Studio 144
Tekmatix NA 199
Towson Valley Motors 202
University of Maryland 196
The Upjohn Co. 157
USAF Recruiting 188
VNA 185
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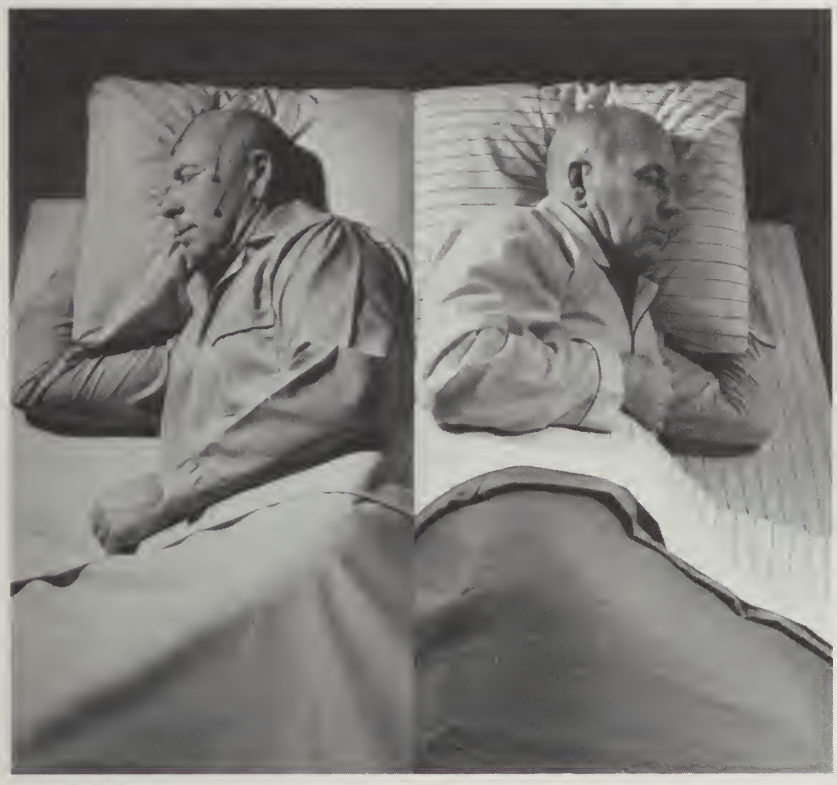
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MISCELLANY

Executive Director's Newsletter 219
Hotline Numbers 245, 274, 288
Medical Miscellany 255, 274, 292
Medicolegal Hotline 266
Change of Address Form 270
Consultation 279
Physician Placement Service 294
Information for Authors 295
T-Shirt Order Form 300
Doctors Take Note 302
Classified Ads 305
Advertisers' Index 307

ARTICLES

Characteristics of Hospitalized TB Patients: Montebello Center, Maryland, 1981 to 1983—Susan M. Bland MD, Randy Berger MD, James P.G. Flynn MD, and Irving I. Kessler MD 259

Osteoarthritis VI: The Hip—Surgical Management—Dennis W. Lennox MD 267

Emergency Treatment of Anaphylactoid Reactions to Radiographic Contrast Materials—Paul G. Mueller MD 277

Curriculum in Ambulatory Care—Julian W. Reed MD 281

High-Pressure Tool Injection Injuries—Michael A. McClinton MD and Stewart Wright MD 289

DEPARTMENTS

Disease Control and Epidemiology Newsletter 223

Annual Meeting Announcements 231

Inside Med-Chi 241

Auxiliary 244

The Library Page 246

Maryland Oncology Newsletter 248

One Minute with Diabetes 249

HBP Commentary 250

Your Medical Faculty at Work 293

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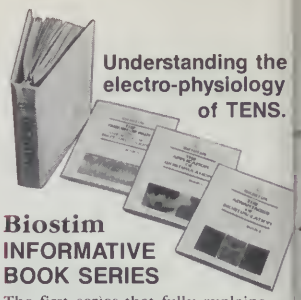
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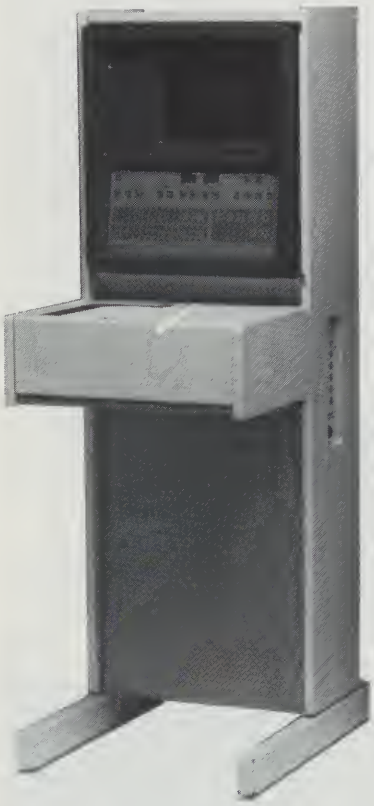
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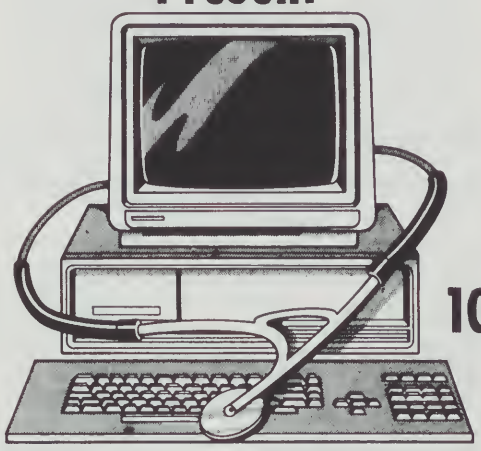


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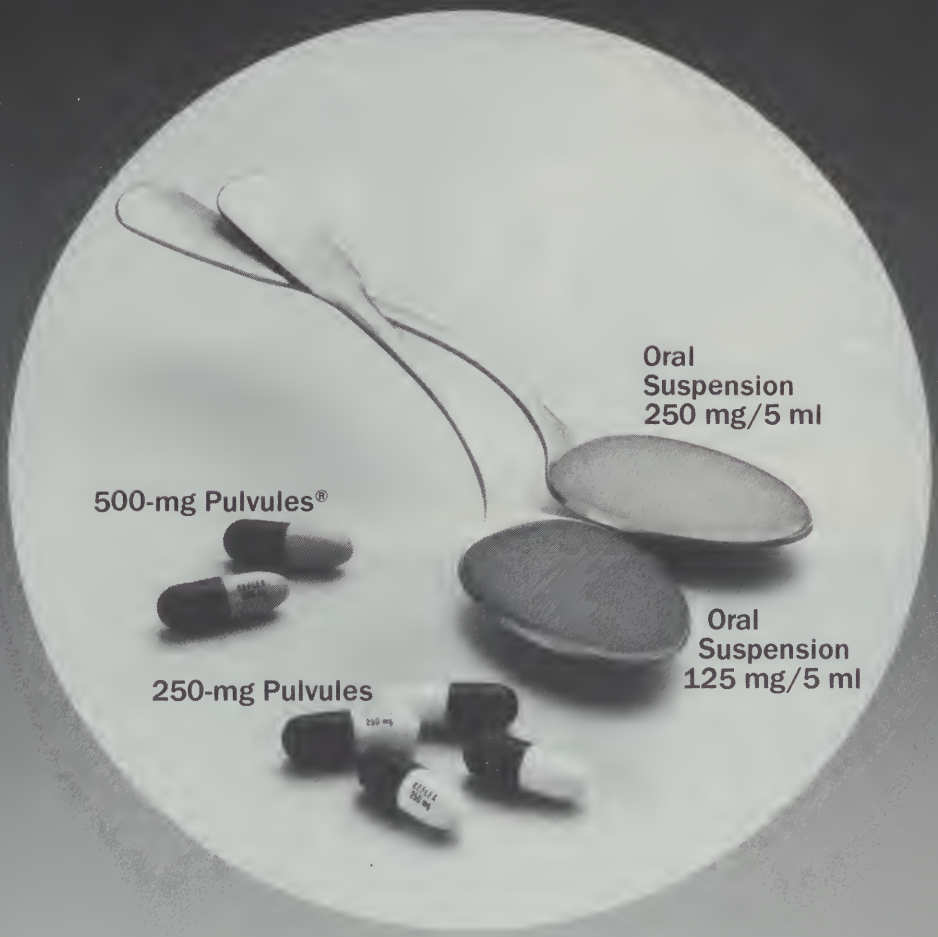
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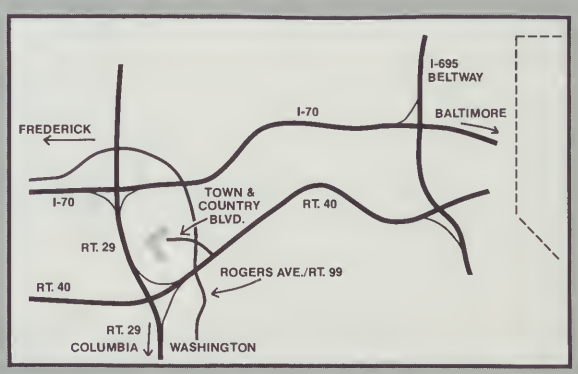


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Executive Director's Newsletter

March 1985

DUAL FEE SCHEDULES

On February 19, 1985, the Faculty's Legal Counsel filed a Petition for Declaratory Ruling with the Commission on Medical Discipline. The Petition asks the Commission to rescind its opinions concerning dual fee schedules or, at the very least, exempt from the opinions physicians who do not participate in Medicare and physicians who do participate in PPOs, HMOs, IPAs, and other similar programs. We expect a favorable ruling imminently and will notify you as soon as the ruling is issued.

TALBOT COUNTY MEETING

Physicians and their spouses throughout Maryland are invited to a special meeting sponsored by the Talbot County Medical Society and its Auxiliary.

Harrison L. Rogers MD, President-elect of AMA, will be guest speaker at the dinner on Thursday, April 11, 1985, 6:30 p.m. His subject will be "American Medicine: A Legislative Prognosis."

The cost is $25 per person. Checks payable to the Talbot County Medical Society should be sent to Mrs. Donald T. Lewers, Talbot County Medical Auxiliary, Route 4, Box 511, Easton, MD 21601. Deadline for reservations is March 30.

ANNUAL MEETING

"Challenge of Change" is the theme of our 1985 Annual Meeting that offers many Scientific Sessions on the newest medical advances as well as two dynamic Plenary Sessions.

Paul M. Ellwood, Jr. MD, President of InterStudy, is keynote speaker for the Plenary Session, "Challenge of Change," on Thursday, April 25 from 4:00 to 5:30 p.m. Dr. Ellwood will address the attendees on how the radical changes now under way in the health industry will affect their practices and their ability to retain patients.

Substance abuse, depression and anxiety, and sexual problems as they relate to physician families will be the focus of the second Plenary Session on Saturday, April 27 at 10:00 a.m.

HOTLINE FOR IMPAIRED PHYSICIANS

A new CARE HOTLINE has been established for reporting physicians who may be impaired due to abuse of alcohol or other drugs, or psychiatric illness. Your call will go directly to the staff person who works with the Committee and will remain confidential as always. An after-hours message recorder also will be available. The new CARE HOTLINE number is

301-727-0120

COST CONTAINMENT LEGISLATION

Within the next few weeks the House will have completed work on the bills in the Governor's Health Care Cost Containment package. The House Environmental Matters Committee worked intensively for a week on six of the bills to ready them for consideration by the full House. The issues in the Task Force package are far-reaching and complex. At this writing it appears the House will deal with 1. A utilization review bill that provides for in-hospital review under certain conditions; 2. A watered-down Health Resources Planning bill designed to enhance the certificate-of-need review process and give some additional powers to the Commission; 3. An emergency moratorium on all certificate-of-need applications until October 1, 1985; 4. A bill to provide incentives for hospitals to merge and consolidate; 5. A compromise certificate-of-need for office equipment including a $600,000 threshold, the ability of private physicians to see hospital inpatients, no CON requirement for replacement equipment; 6. A state affordability limit bill that has no real support.

It is also likely the legislature will act on a method to collect physician practice pattern data. The Faculty has proposed a number of amendments that would guarantee the confidentiality of the data and provide for the appropriate review and dissemination of it.

REFERENCE COMMITTEE MEETING

There will be two resolutions considered by the Reference Committee at its public hearing on

THURSDAY, APRIL 4, 1985, 7:30 p.m.

in the Faculty Building. All members are invited to attend to discuss the following resolutions:

Resolution 1A/85 - Rejection of Maryland Foundation for Health Care Document Containing a List of Surgical Procedures and Diagnoses or Symptoms for which Inpatient Hospital Care is Denied (introduced by 30 members of Baltimore City, Baltimore County and Harford County Medical Societies)

Resolution 2A/85 - Improving the Public's Perception of Physicians (introduced by Baltimore City Medical Society)

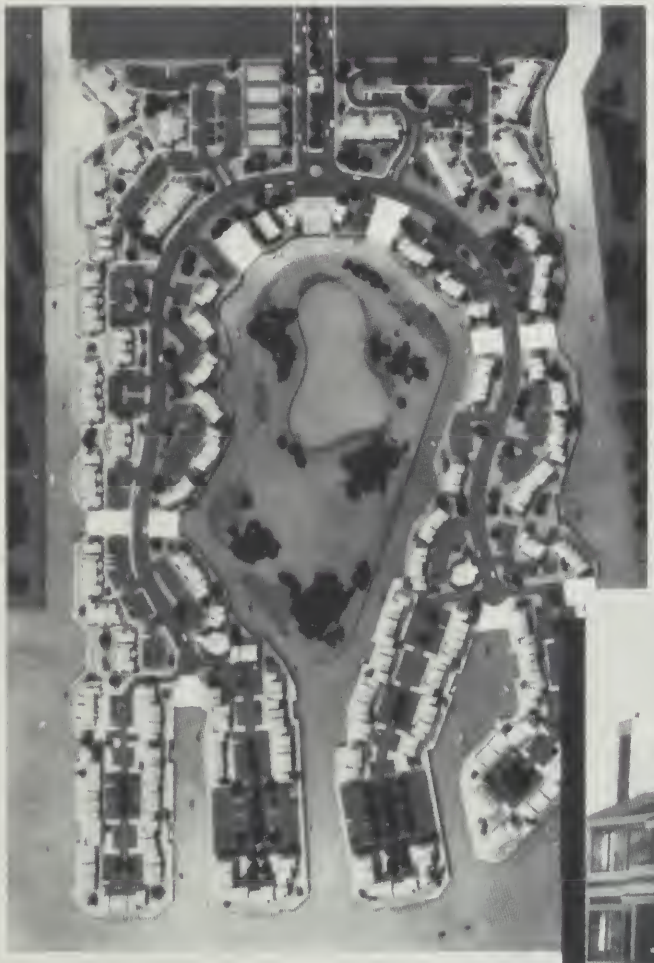
NATIONAL SURVEY

The 1985 National Ambulatory Medical Care Survey is under way. About 5,000 physicians who provide office ambulatory care are included in the sample. Physicians are urged to cooperate if they are contacted on this matter.

John Sargeant
Executive Director

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*JAMA, Volume 248, No. 3, pages 336-339
Yearbook of Medicine, 1983, pages 66-67
Infectious Diseases, 1 84, pages 4-5, 8-9, 11

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PREVENTIVE MEDICINE ADMINISTRATION
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MARCH 1985

UPDATE ON HTLV-III TESTING

Precautions in the Workplace

I. Health Care Employees:

Although the risk of transmission of HTLV-III from an infected health care worker to a susceptible patient is presumed to be low, the potential for transmission exists. Until additional data are available, it is reasonable to apply the Centers for Disease Control (CDC) Guidelines for Infection Control in Hospital Personnel concerning acute hepatitis B infection and HBsAg carriers to persons infected with HTLV-III:

The asymptomatic (person with antibody to HTLV-III) and the persons with AIDS or ARC do not appear to endanger susceptible persons except through direct inoculation of his or her blood or contaminated secretions. Thus, these persons need not be restricted from patient-care responsibilities, unless there is epidemiologic evidence that the worker is transmitting infection.

Personnel who are HTLV-III antibody positive or who have AIDS or ARC may be able to reduce or eliminate their risk of infecting patients by wearing gloves during high-risk procedures in which their blood or body fluids may contact patients. Double-gloving during complex surgery might also help interrupt transmission. Furthermore, it is crucial to counsel persons with AIDS, ARC, and persons with antibody to HTLV-III about practicing good personal hygiene, preventing their blood and potentially infective body fluids from contracting other persons, and not donating blood.

Institutional guidelines may be followed if they are more rigorous than the above recommendations.

II. Non-Health Care Employees:

For persons other than health care workers, there is no public health concern which should prevent infected persons from

performing their work. General infection control recommendations mentioned in section I, should be followed at the workplace.

III. Health Care for Infected Patients:

When seeking medical or dental care for intercurrent illness, infected persons should inform their health care providers of their diagnosis or their positive antibody status so that appropriate evaluation can be undertaken and precautions taken to prevent transmission to others.

Blood and body fluid precautions as outlined by the CDC and by the Task Force at the University of California, San Francisco, should be followed during the care of any infected person. These precautions generally parallel those recommended for cases and carriers of hepatitis B.

Resuscitation bags or disposable devices for mouth-to-mouth cardiopulmonary resuscitation should be available for every infected patient admitted to the hospital, as is recommended for cases of hepatitis B, tuberculosis, and other potentially transmissible infections.

Procedures for cleaning environmental surfaces and endoscopy equipment contaminated by an infected patient in the hospital should be similar to those recommended for patients with hepatitis B. Devices that have punctured the skin, such as hypodermic and acupuncture needles, should be disposable or should be steam sterilized by autoclave before reuse or safely discarded.

Source

Guidelines were prepared by CDC, Atlanta, Georgia, adapted and expanded by the Baltimore City Health Department and agreed to by the Maryland State AIDS Task Force of the Maryland Department of Health and Mental Hygiene.

ADDITIONAL IMMUNIZATION VISITS-POOR MEDICAL PRACTICE

Representatives of the Department of Health and Mental Hygiene (DHMH) examined immunization records of eight Day Care and eight Head Start Centers. Results of an immunization level survey of two-year old children were also examined. This was done in an effort to determine the extent of Maryland physicians who were administering measles, mumps, and rubella (MMR) vaccines separately, instead of the recommended combined MMR antigen. A total of 2,499 records were examined. On 166 occasions, MMR vaccines were given separately. Eighty-nine (89) physicians were identified as the presumed providers of the vaccine; all but nine were pediatricians. The other specialities were: Family Practice (6); General Practice (1); and Internal Medicine (2).

A second disturbing factor was discovered from the examination of these records. While it was not the intent of the review, it quickly became evident that if the physician administered the MMR vaccines

separately, there was a good chance that DTP and OPV were also given during separate visits. This results in unnecessary generation of additional visits to the physician's office, along with additional costs and trauma to the patient. Specifically, in 51 of the 166 cases where MMR vaccines were separated, DTP and OPV were also separated, resulting in as many as seven excess visits to complete an immunization schedule.

After the above information was collected, 15 of the physicians whose names appeared most often on records where MMR vaccines were administered separately were contacted. The purpose was to confirm the findings on the records and to elicit the physician's justification for such a practice. Only one physician denied that he administered the antigens separately. Other justifications included: concern for efficacy of the combined vaccine and for avoiding adverse reactions (4); following the practice of other area colleagues (3); a belief that parents were better able to pay three smaller bills rather than one large bill (3); to accomodate office administrative costs (2); and to complete the immunization schedule that was begun by another physician who administered the antigens separately (2).

The DHMH is concerned that the results of the immunization records in 16 Day Care and Head Start Centers may be reflective of a much larger practice that is occurring in Maryland. Regardless of the reasons for separating the antigens, there is very little advantage to the patient who receives MMR vaccines separately. On the contrary, there are numerous disadvantages and potential dangers to a child.

Administering MMR vaccines separately results in: 1) delaying the complete protection to all three diseases leaving a child unprotected for a longer period of time than necessary; 2) the possibility that the patient will drop out of the health care system before the immunizations are completed; 3) three visits to the physician's office rather than one; 4) a possibility of three large medical bills (in contrast to three small bills) rather than one large one; 5) three injections (occasions of trauma) rather than one; 6) a far more complicated immunization record than necessary to document and retain; 7) a possibility of three adverse reactions rather than one; 8) an additional cost to the taxpayers in the cases of medical assistance patients; and 9) excess paper work to process.

Physicians using the single vaccines instead of MMR (or otherwise deviating from the nationally recommended immunization schedule) are acting directly against the medical advice of the AAP, the ACIP, the Med-Chi, and DHMH. It is strongly advised that physicians adhere to the nationally published recommendations for all immunizations.

IMPROVED IMMUNIZATION STANDARDS FOR SECONDARY SCHOOLS

A significant amendment to Maryland's School Immunization Regulation was adopted February 11, 1985. The amendment broadens the requirements for pupils in grades 7-12. Formerly, pupils in these grades were only required to prove immunity to measles. Proof of

immunity against polio, diphtheria, tetanus, and rubella will now be required in addition to measles for grades 7-12.

For grades K-6, the compliance standard will remain the same. Children must be immunized in accordance with the Recommended Schedule of Immunization approved by the Med-Chi and the Department of Health and Mental Hygiene. The current approved schedule conforms to the recommendations of the American Academy of Pediatrics (AAP).

For grades 7-12, the compliance criteria will be:

Diphtheria and Tetanus:	3 doses with one dose given on or after the 4th birthday
Polio:	3 doses of OPV (or 4 doses of IPV) with one dose given on or after the 4th birthday
Measles:	1 dose given on or after the first birthday or a titer of 1:4 or greater
Rubella:	1 dose or a titer of 1:8 or greater

The new requirements will be effective in September 1985 for grades 7 through 9 and no later than September 1986 for grades 10 through 12. The majority of students in these grades already have immunization certificates on file which document the newly required immunizations. However, there will be pupils who have to obtain immunization records or vaccinations. With good cooperation between the medical community and the schools, this significant improvement in school health standards should be accomplished without disruption of school or health services.

PERTUSSIS LEGISLATION

House Bill 520 - Pertussis, was passed during the last Legislative session, was signed into law by the Governor and was to become effective on January 1, 1985. However, until the Maryland Department of Health and Mental Hygiene, in conjunction with the Med-Chi and the Dissatisfied Parents Together Organization, promulgates Guidelines for implementation, the provisions of the law cannot be carried out. These Guidelines are expected to be proposed for publication in the Maryland Register during early March, then to be followed by a public comment period and a public hearing prior to their being officially adopted. Only after these events are accomplished can the provisions of the Bill be assigned and implemented. In general, the provisions call for providing pertussis information to new mothers and before any pertussis vaccine is administered. It also requires that the details of any adverse reactions to pertussis vaccine be recorded in the individual's permanent medical record, that the reaction be investigated and be reported through a designated channel to the Centers for Disease Control (CDC) and the vaccine manufacturer. The earliest these Guidelines can be promulgated through the Administrative Procedures Act would be June 1985.

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187TH ANNUAL MEETING

The Challenge of CHANGE

Thursday Plenary Session ▪ April 25, 1985 - 4:00 - 5:30 p.m.

Paul M. Ellwood, Jr., M.D. President of Interstudy, will address the attendees on how the radical changes now underway in the health industry will affect their practices and their ability to retain patients.

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187th ANNUAL MEETING

Thursday–Saturday, April 25–27, 1985

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THURSDAY, APRIL 25, 1985

8:30 a.m.
COUNCIL

9:30 a.m.
HOUSE OF DELEGATES
All members are invited to attend.

8:45 a.m.
LEGISLATION POLICY WITH REGARD TO PHYSICIAN ASSISTANTS, **F. Lynn May,** Arlington, VA and **Curtis Decker,** Annapolis

PRESENT UTILIZATION OF PHYSICIAN ASSISTANTS
Education and Training, Robert Solomon PA-C, Baltimore; **Surgical Physician Assistants, Jeffrey Stark PA-C,** Baltimore; **Physician Assistants Used as Medical Housestaff, Bernard Tabatznik MD,** Baltimore; **Emergency Room Physician Assistants, Wayne S. Barry MD,** Baltimore;

FUTURE ROLE OF PHYSICIAN ASSISTANTS IN THE HEALTH CARE DELIVERY SYSTEM, **James Cawley PA,** Washington DC, **Karl Katterjohn PA-C,** Baltimore and **Gretchen Shafft PhD,** Baltimore, Maryland Academy of Physician Assistants

12:15 p.m.
PRAYER LUNCHEON
Pastoral Care: Profession, Plebeian Career, or Placebo? The Reverend Grady F. W. Barbour, Linthicum, Committee on Medicine and Religion/Med-Chi

1:00 p.m.
The Field Liaison for the American College of Surgeons Meeting—All Liaison Fellows and Associate Fellows are Invited to Attend

2:00 p.m.
DEALING WITH THE SOMATIZING PATIENT
Somatization: Diagnosis and Management, Charles V. Ford MD, Nashville, TN; **Somatization: Impact Upon the Patient's Family, Lee Randol Barker MD,** Baltimore, The Maryland Psychiatric Society, Inc.

Emotional Development in the First Eighteen Months: Principles of Intervention and Clinical Diagnosis in Infancy, Serena Wieder PhD, Silver Spring, Maryland Chapter, American Academy of Pediatrics/Infant, Child & Adolescent Health Subcommittee/Med-Chi

Introductory Remarks, Paul Bormel MD, Baltimore; **Joseph S. McLaughlin MD,** Baltimore—**Moderator; Pancreatic Transplantation, Frederick R. Bentley MD,** Baltimore; **Breast Reconstruction After Mastectomy—Immediate versus Delayed, Nelson H. Goldberg MD,** Baltimore; **Application of the Laser to Surgery, William C. Gray MD,** Baltimore, Maryland Chapter, American College of Surgeons

Aneurysmal Subarachnoid Hemorrhage—An Update, Harold P. Adams, Jr. MD, Iowa City, IA, American Heart Association, Maryland Affiliate/Stroke Working Group

The Role of Food Hypersensitivity and Atopic Dermatitis, Hugh A. Sampson MD, Durham, NC, Maryland Asthma and Allergy Society

Endoscopy Update 1985, David Fleischer MD, Washington DC, Maryland Society of Gastrointestinal Endoscopy

Keeping the Elderly Functional and Fit, Franz U. Steinberg MD, St. Louis, MO, Maryland Society of Physical Medicine and Rehabilitation

EFFECTIVE COMMUNICATION CAN REDUCE YOUR RISKS OF MEDICAL LIABILITY, **Marlyn D. Boyd PhD,** Columbia, SC and **Allen Douma MD,** Washington DC, Center for Health Education

4:00 p.m.
PLENARY SESSION
THE CHALLENGE OF CHANGE, **Paul M. Ellwood, Jr. MD,** Excelsior, MN

FRIDAY, APRIL 26, 1985

8:45 a.m.
BREAKFAST AND LEARN

FUTURE PERSPECTIVES OF OTOLARYNGOLOGY—HEAD AND NECK SURGERY
Richard R. Gacek MD Syracuse, NY, Maryland Society of Otolaryngology—Head and Neck Surgery

HELPING YOUR PATIENTS CONTROL THEIR BLOOD LIPIDS
Introduction, Frank Franklin MD, Baltimore; **When and How to Evaluate a Patient's Lipids, Thomas Pearson MD,** Baltimore; **What Can be Learned from a Family History & Apoprotein Measurements, Peter Kwiterovich MD,** Baltimore; **What Diet Should I Recommend? Frank Franklin MD;** Questions and Answers

Break

Introduction, Frank Franklin MD, Baltimore; **How to Help Patients Change Habits and Lose Weight, Kelly Bronwell PhD,** Philadelphia, PA; **Positive and Negative Aspects of Exercise Training: How to Start and Maintain Patients in an Exercise Program, Andrew Goldberg MD,** Baltimore; **How to Help Patients to Stay on Diets in Everyday Life, Ginny Hartmuller MS,** Baltimore; **When and How to Begin Lipid Lowering Medications, Simeon Margolis MD,** Baltimore, American Heart Association, Maryland Affiliate, Inc.

Respiratory Failure and Chronic Obstructive Pulmonary Disease, Peter Terry MD, Baltimore; **Emphysema, Pathogenesis and Future Therapy, Ronald G. Crystal MD,** Bethesda, Maryland Thoracic Society

3rd Annual Meeting of the Directors of Medical Education, Continuing Medical Education Review Committee/Med-Chi

Topic to be Announced, William R. Irby MD, Richmond, VA, Maryland Society for the Rheumatic Diseases/Pfizer Laboratories

10:45 a.m.
The Challenge of Change: Governmental and Socioeconomic Changes in the Health Field, Peyton E. Weary MD, Charlottesville, VA, Maryland Dermatologic Society

Tissue Expanders, John B. McCraw MD, Norfolk, VA, The John Staige Davis Society of Plastic Surgeons of Maryland

THE PHYSICIAN, HIS PATIENT, AND THE WORKPLACE
Post-Coronary By-Pass Patients: Their Ability to Return to Work, Phillip Achuff MD, Baltimore; **Radiology's Role in the Diagnosis of Abestosis, Paul S. Wheeler MD,** Baltimore; **Prescription Medicines: How They Affect the Ability to Work, Michael Spodak MD,** Baltimore, Maryland Occupational Medical Association/Occupational Health Committee/Med-Chi

Legal and Ethical Issues in the Termination of Treatment, Neal M. Friedlander MD, Baltimore, Maryland Lung Association of Maryland

Topic to be Announced, Kenneth H. Williams MD, Ft. Washington, PA, Committee on Physician Rehabilitation/Committee on Alcoholism/Med-Chi

12:15 p.m.
LUNCH AND LEARN

2:00 p.m.
UPDATE ON HIGH BLOOD PRESSURE: 1985
New Drugs and Old Favorites: What to Choose, Ray W. Gifford Jr. MD, Cleveland, OH; **The Five-Hour Office Blood Pressure Check: An Alternative to Hospitalization, Lee Randol Barker MD,** Baltimore; **The New Division of Hypertension: The University of Maryland School of Medicine, Elijah Saunders MD,** Baltimore; **The Role of Calcium, Sodium, and Other Nutrients in Blood Pressure Regulation, Michael J. Horan MD,** Bethesda; **The Systolic Hypertension in the Elderly Program (SHEP), Roger Sherwin MD,** Baltimore; **JNC III: Changes in HBP Referral and Guidelines, Donald O. Fedder DrPH,** Baltimore, Maryland High Blood Pressure Commission

RESOLVING AND AVOIDING MEDICAL STAFF CONFLICTS IN MULTI-SPECIALTY HOSPITALS: A MARKETING APPROACH, **Andrew P. Morley MD,** Decatur, GA and **Ellen J. Belzer,** Kansas City, MO, Maryland Academy of Family Physicians

SPOUSE ABUSE—**Honorable Martha Wyatt,** Annapolis—**Moderator**
Domestic Violence, Honorable John J. Bishop Jr., Towson; **Legal Resources Available to Battered Spouses, L. Tracy Brown, Esquire,** Baltimore; **Why Does She Stay? Harriet Douglas LCSW,** Annapolis; **Medical Aspects of Domestic Violence, Bruce L. Regan MD,** Baltimore; **Clinical Research on Consequences of Criminal Sanctions for Domestic Violence: Implications for Medical Practice and Ethics, Lawrence W. Sherman PhD,** College Park, Office of the Attorney General for the State of Maryland/Med-Chi

DEMONSTRATION OF A MEDICOLEGAL TRIAL INVOLVING TRAUMATIC CHRONIC PAIN SYNDROME
Elliott Fishel MD, Medical Moderator—**H. Albert Korn, Esquire,** Legal Moderator

Physicians
Don M. Long MD, Baltimore, **Paul McAffee MD,** Baltimore, **Godfrey Pearlson MD,** Baltimore, **David Conblath MD,** Baltimore

Judges
The Honorable Robert L. Karwacki, Annapolis, **The Honorable John P. Corderman,** Washington County, **The Honorable John F. McAuliffe,** Montgomery County

Attorneys
Charles M. Tobin, Esquire, Montgomery County, **Stuart M. Salsbury, Esquire,** Baltimore, **John E. Sandbower III Esquire,** Baltimore, **Patti G. Zimmerman, Esquire,** Baltimore, **George J. Goldsborough Jr., Esquire,** Talbot County

Critique
Elliott Fishel MD
William G. Speed III MD
Medicolegal Committee/Med-Chi

Changing Gears to Meet the Challenge of the Geriatric Imperative, William R. Hazzard MD, Baltimore Long Term Care and Geriatrics Committee/Med-Chi

Challenges In Choosing the Best Treatment for the Emotionally Disturbed Adolescent, Jay LeBow MD, Ellicott City, Taylor Manor Hospital

Quality, Technology and Malpractice: Are We Victims of Our Own Devices? William F. Jessee MD, Chapel Hill, NC, Medical Mutual Liability Insurance Society of Maryland

THE HORIZONS OF CHANGE IN ORTHOPEDICS
New Concepts in the Diagnosis and Treatment of Wrist Injuries, Gaylord L. Clark MD, Baltimore; **Michael McClinton MD** Baltimore; **Over the Orthopedic Rainbow, John Gordon MD,** Baltimore, Maryland Orthopaedic Society

4:00 p.m.
Smoking—the #1 Health Problem, Edward N. Brandt Jr. MD, Baltimore, Committee on Preventive Medicine and Public Health/Med-Chi

Acute Post-Operative Hypertension, Leigh Thompson MD, Indianapolis, IN, Maryland-DC Society of Anesthesiologists

APPROACH TO SWALLOWING PROBLEMS: A PANEL DISCUSSION
Neurology, David W. Bucholz MD, Baltimore; **Radiology, Martin W. Donner MD,** Baltimore; **Otolaryngology, Haskins Nashima MD,** Baltimore; **Gastroenterology, William J. Ravich MD, Rehabilitation Medicine, Arthur Siebens MD,** Baltimore, The Johns Hopkins Swallowing Clinic

Bone Imaging in the Study of Pleasure and Pain, Lawrence E. Holder MD, Baltimore, Maryland Society of Nuclear Medicine
Maryland Society of Eye Physicians and Surgeons

SATURDAY, APRIL 27, 1985

8:30 a.m.
Ovarian Echos, Peter L. Cooperberg MD, Vancouver, Canada; **Fetal Intervention, David Graham MD,** Rochester, NY, Maryland Radiological Society/ Obstetrical and Gynecological Society of Maryland

8:45 a.m.
Changing Concepts in Pathology—With Particular Emphasis on Urological Pathology, Fathollah K. Mostofi MD, Washington DC, Maryland Society of Pathologists

PRO: How Will it Affect Your Patients, Everet F. Bryant, Philadelphia, PA; **Leon Kassel MD,** Baltimore; **Bert Harrell,** Baltimore, Public Relations Committee/ Med-Chi

10:45 a.m.
PLENARY SESSION
PHYSICIANS AND THEIR FAMILIES
Commonly Encountered Problems in the Families of Physicians, William L. Webb Jr. MD, Baltimore

Panel:
J. D. Drinkard MD, Moderator
Sexual Problems, Emile A. Bendit MD, Baltimore
Issues of Substance Abuse, Sheldon I. Miller MD, Baltimore
Depression and Anxiety, Dean Schuyler MD, Baltimore Sheppard and Enoch Pratt Hospital

12:30 p.m.
MMPAC LUNCHEON
Year of the Doctor: Winners or Losers? The Honorable Larry Young, Chairman House Environmental Matters Committee, Maryland General Assembly

2:00 p.m.
House of Delegates

7:30 p.m.
Presidential Reception and Banquet

FRIDAY, 8:45-10:15 AM

BREAKFAST AND LEARN

1B. Current Treatment of Epilepsy
Gregory K. Bergey MD, Assistant Professor of Neurology and Physiology, University of Maryland School of Medicine

2B. Biofeedback and Management of Stress Incontinence
Kathryn Larsen Burgio PhD, Senior Staff Fellow, Gerontology Research Center, National Institute on Aging, Francis Scott Key Medical Center

3B. Management of the Frail Geriatric Patient Who Is Home Bound
John R. Burton MD, Director, Division of Geriatric Medicine, Francis Scott Key Medical Center

4B. Update on Shock Trauma
Ameen Ramzy MD, M.I.E.M.S.S.

5B. Prenatal Diagnosis of Genetic Disease
Malmon M. Cohen PhD, Professor of Obstetrics & Gynecology and Pediatrics, University of Maryland School of Medicine; Division of Human Genetics, University of Maryland Hospital

6B. Sensible Management of Anemias
C. Lockard Conley MD, Distinguished Service Professor of Medicine, Emeritus, The Johns Hopkins University School of Medicine

7B. Update on Menopause
Gay Guzinski MD, Director, Division of Gynecology, University of Maryland Hospital

8B. Hepatitis Update
Frank L. iber MD, Professor of Medicine, University of Maryland School of Medicine, Chief, Division of Gastroenterology, University of Maryland Hospital and Baltimore Veterans Administration Medical Center

9B. Commission on Medical Discipline
Hilary T. O'Herlihy MD FACC FCCP, Chairman of the Commission on Medical Discipline

10B. Status of Abortions in Maryland
J. Courtland Robinson MD, Medical Director, Planned Parenthood of Maryland

11B. PPO's
David M. Soloman MD

12B. Update on Migraine
William G. Speed III MD FACP, Associate Professor of Medicine, The Johns Hopkins School of Medicine

FRIDAY, 12:15-1:45 PM

LUNCH AND LEARN

13L. Rheumatic Diseases and Anti-Inflammatory Drugs
Lynn Billingsly MD, Instructor of Medicine, Division of Rheumatology, The Johns Hopkins University School of Medicine

14L. Update on AIDS
Frank M. Calia MD, Professor and Vice Chairman, Department of Medicine, University of Maryland School of Medicine; Chief, Medical Services, Baltimore Veterans Administration Medical Center

15L. Behavioral Pediatrics
Lois T. Flaherty MD, Director, Division of Child and Adolescent Psychiatry, University of Maryland Hospital

16L. Update on Acne
Ronald Goldner MD, Assistant Professor of Dermatology, University of Maryland School of Medicine

17L. Improving Surgical Care of Children
J. Alex Haller Jr. MD, Robert Garrett Professor of Pediatric Surgery, The Johns Hopkins University School of Medicine

18L. Sudden Death Cardiac Arrhythmias
John A. Kastor MD, Theodore E. Woodward Professor of Medicine, Chairman, Department of Medicine, University of Maryland School of Medicine; Physician in Chief, University of Maryland Hospital

19L. Legislative Update
Senator Francis X. Kelly, Member, Senate Budget and Taxation Committee

20L. Use of Drugs in Alcoholic Patients
Michael Potash MD, Instructor of Psychiatry, The Johns Hopkins University School of Medicine; Former Chairman, Governor's Advisory Commission of Drug Abuse

21L. Inflammatory Bowel Disease
David M. Saltzberg MD, Assistant Professor of Medicine, Division of Gastroenterology, University of Maryland School of Medicine

22L. Retirement Planning
Jacques T. Schlenger, Esquire, Managing Partner, Venable, Baetjer and Howard

23L. Sexual Abuse of Children
Charles I. Shubin MD, Chief of Pediatrics, Lutheran Hospital of Maryland, Chairman, Governor's Task Force on Child Abuse and Neglect

24L. PRO—Where It Stands and Where It May Go
Kennard Yaffe MD, Chairman, Baltimore City PSRO; Medical Director, Maryland Foundation for Health Care

MEAL FUNCTIONS RESERVATION FORM

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Everyone who makes a reservation for a meal function is preregistered for the meeting. Please pick up your registration packet which will include your badge, all tickets you have requested, and other pertinent material for the meeting, at the Advance Registration Desk, Rear of the Exhibit Hall, Valley Ballroom, Lower Level, Hunt Valley Inn. **TICKETS WILL NOT BE MAILED.**

No. of Tickets — **Amount**

____ **PRAYER LUNCHEON** $____
Thurs., April 25—12:15 PM.
$13.00 per person

____ **BREAKFAST AND LEARN** $____
Fri., April 26—8:45 AM
$13.00 per person

____ **LUNCH AND LEARN** $____
Fri., April 26—12:15 PM.
$13.00 per person

MY CHOICES OF TABLES ARE: (please assist us by clearly indicating both the number of the tables and the corresponding letter.)

1st _____ 3rd _____
2nd _____ 4th _____

A description of tables is listed elsewhere in the program.

NAME: _____
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CITY _____ STATE _____ ZIP _____
TELEPHONE (DAY) _____
COUNTY SOCIETY _____

No. of Tickets — **Amount**

____ **AUXILIARY LUNCHEON** $____
Fri., April 26—1:00 PM
$14.50 per person

____ **MMPAC LUNCHEON** $____
Sat., April 27—12:30 PM
$15.00 per ticket
(If you are a Sustaining member, one ticket will be free. Remember, Sustaining Members are those who pay an additional amount beyond the regular MMPAC dues)

____ **PRESIDENTIAL RECEPTION & BANQUET** $____
Sat., April 27—7:30 PM
If you wish to be seated with specific individuals, please indicate on a separate sheet and attach
$40.00 per person

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April 25–27, 1985

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CANCELLATIONS In the unfortunate event that it becomes necessary to cancel a reservation, your deposit will be refunded (or, in case of a guaranteed reservation, the guarantee nullified) upon notice 48 hours in advance of your scheduled arrival.

Check-In Time is 4 P.M. Check-Out Time is 1 P.M.

Deadline for Reservations: March 24, 1985

Med-Chi Photo Contest Rules

Eligibility

All members of the Faculty and members of the Auxiliary to the Medical and Chirurgical Faculty may enter. Professional photographers may not enter. Members of the Photo Contest Committee and their families are not eligible.

Contest Rules

1. Photographs may be submitted in two categories—BLACK and WHITE or COLOR.
2. Limit: three entries per person.
3. Entries must have name, address, and telephone number attached to the back of each photograph.
4. PRINTS only, no smaller than 8 × 10 or larger than 11 × 14, will be accepted. If your favorite shot is a slide, you must have a print made within these size ranges to enter in the contest.
5. Entries may be mailed or brought to the Faculty Office, 1211 Cathedral Street, Baltimore, Maryland 21201 by the close of the business day on March 27, 1985.
6. Entries MUST be matted or dry mounted. No framed photographs will be accepted.
7. Photographs entered in the contest will be on display at the Annual Meeting in April 1985.
8. Winners will be announced at the Annual Meeting of the Medical and Chirurgical Faculty, April 25 thru 27, 1985.
9. Photographs will NOT be mailed back. Photographs may be claimed at the exhibit area at the close of the Annual Meeting on Saturday, April 27 at noon or at the Faculty Building thereafter.
10. The Faculty does not guarantee against loss or damage of any kind to the photographs submitted to the contest.
11. Prizes will be awarded to the FIRST and SECOND place winners. Additional information about the prizes will be published in the JOURNAL.

CALL FOR PAPERS
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Southampton Princess Hotel, Bermuda
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DEADLINE FOR ABSTRACTS: FRIDAY, MAY 3, 1985

The Semiannual Meeting attracts physicians from many different specialties, most of whom are engaged in private practice. The papers submitted should present a clinical subject of interest to a wide variety of practitioners. Each presentation will be approximately an hour in length.

All interested presenters are requested to send an abstract of approximately 150 words prior to FRIDAY, MAY 3, 1985 to:

C. Earl Hill MD, Chairman
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Medical and Chirurgical Faculty of the State of Maryland
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INDICATIONS AND USAGE: These preparations are indicated for the treatment of infections caused by susceptible strains of designated microorganisms as follows: Respiratory Tract Infections (e.g., tonsillitis, pharyngitis, and lobar pneumonia) due to *S. pneumoniae* (formerly *D. pneumoniae*) and group A beta-hemolytic streptococci [penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever; Velosef (Cephradine, Squibb) is generally effective in the eradication of streptococci from the nasopharynx; substantial data establishing the efficacy of Velosef in the subsequent prevention of rheumatic fever are not available at present]; Otitis Media due to group A beta-hemolytic streptococci, *H. influenzae,* staphylococci, and *S. pneumoniae*; Skin and Skin Structures Infections due to staphylococci and beta-hemolytic streptococci; Urinary Tract Infections, including prostatitis, due to *E. coli, P. mirabilis, Klebsiella* species, and enterococci (*S. faecalis*).

Note: Culture and susceptibility tests should be initiated prior to and during therapy.

CONTRAINDICATIONS: In patients with known hypersensitivity to the cephalosporin group of antibiotics.

WARNINGS: *Use cephalosporin derivatives with great caution in penicillin-sensitive patients since there is clinical and laboratory evidence of partial cross-allergenicity of the two groups of antibiotics; there are instances of reactions to both drug classes (including anaphylaxis after parenteral use).* In persons who have demonstrated some form of allergy, particularly to drugs, use antibiotics, including cephradine, cautiously and only when absolutely necessary.

Pseudomembranous colitis has been reported with the use of cephalosporins (and other broad spectrum antibiotics); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use. Treatment with broad spectrum antibiotics alters normal flora of the colon and may permit overgrowth of clostridia. Studies indicate a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis. Cholestyramine and colestipol resins have been shown to bind the toxin *in vitro*. Mild cases of colitis may respond to drug discontinuance alone. Manage moderate to severe cases with fluid, electrolyte and protein supplementation as indicated. Oral vancomycin is the treatment of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile* when the colitis is severe or is not relieved by drug discontinuance; consider other causes of colitis.

PRECAUTIONS: General: Follow patients carefully to detect any side effects or unusual manifestations of drug idiosyncrasy. If a hypersensitivity reaction occurs, discontinue the drug and treat the patient with the usual agents, e.g., pressor amines, antihistamines, or corticosteroids. Administer cephradine with caution in the presence of markedly impaired renal function. In patients with known or suspected renal impairment, make careful clinical observation and appropriate laboratory studies prior to and during therapy as cephradine accumulates in the serum and tissues. See package insert for information on treatment of patients with impaired renal function. Prescribe cephradine with caution in individuals with a history of gastrointestinal disease, particularly colitis. Prolonged use of antibiotics may promote the overgrowth of nonsusceptible organisms. Take appropriate measures should superinfection occur during therapy. Indicated surgical procedures should be performed in conjunction with antibiotic therapy.

Information for Patients: Caution diabetic patients that false results may occur with urine glucose tests (see PRECAUTIONS, Drug/Laboratory Test Interactions). Advise the patient to comply with the full course of therapy even if he begins to feel better and to take a missed dose as soon as possible. Tell the patient he may take this medication with food or milk since G.I. upset may be a factor in compliance with the dosage regimen. The patient should report current use of any medicines and should be cautioned not to take other medications unless the physician knows and approves of their use (see PRECAUTIONS, Drug Interactions).

Laboratory Tests: In patients with known or suspected renal impairment, it is advisable to monitor renal function.

Drug Interactions: When administered concurrently, the following drugs may interact with cephalosporins:

Other antibacterial agents — Bacteriostats may interfere with the bactericidal action of cephalosporins in acute infection; other agents, e.g., aminoglycosides, colistin, polymyxins, vancomycin, may increase the possibility of nephrotoxicity.

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Diuretics (potent "loop diuretics," e.g., furosemide and ethacrynic acid) — Enhanced possibility for renal toxicity.

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Drug/Laboratory Test Interactions: After treatment with cephradine, a false-positive reaction for glucose in the urine may occur with Benedict's solution, Fehling's solution, or with Clinitest® tablets, but not with enzyme-based tests such as Clinistix® and Tes-Tape®. False-positive Coombs test results may occur in newborns whose mothers received a cephalosporin prior to delivery. Cephalosporins have been reported to cause false-positive reactions in tests for urinary proteins which use sulfosalicylic acid, false elevations of urinary 17-ketosteroid values, and prolonged prothrombin times.

Carcinogenesis, Mutagenesis: Long-term studies in animals have not been performed to evaluate carcinogenic potential or mutagenesis.

Pregnancy Category B: Reproduction studies have been performed in mice and rats at doses up to 4 times the maximum indicated human dose and have revealed no evidence of impaired fertility or harm to the fetus due to cephradine. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, use this drug during pregnancy only if clearly needed.

Nursing Mothers: Since cephradine is excreted in breast milk during lactation, exercise caution when administering cephradine to a nursing woman.

Pediatric Use: Adequate information is unavailable on the efficacy of b.i.d. regimens in children under nine months of age.

ADVERSE REACTIONS: Untoward reactions are limited essentially to G.I. disturbances and, on occasion, to hypersensitivity phenomena. The latter are more likely to occur in persons who have previously demonstrated hypersensitivity and those with a history of allergy, asthma, hay fever, or urticaria.

The following adverse reactions have been reported following use of cephradine: G.I. — Symptoms of pseudomembranous colitis can appear during antibiotic therapy; nausea and vomiting have been reported rarely. Skin and Hypersensitivity Reactions — mild urticaria or skin rash, pruritus, joint pains. Hematologic — mild transient eosinophilia, leukopenia and neutropenia. Liver — transient mild rise of SGOT, SGPT, and total bilirubin with no evidence of hepatocellular damage. Renal — transitory rises in BUN have been observed in some patients treated with cephalosporins; their frequency increases in patients over 50 years old. In adults for whom serum creatinine determinations were performed, the rise in BUN was not accompanied by a rise in serum creatinine. Others — dizziness, tightness in the chest, and candidal vaginitis.

DOSAGE: Adults — For respiratory tract infections (other than lobar pneumonia) and skin and skin structure infections: 250 mg q. 6 h or 500 mg q. 12 h. For lobar pneumonia: 500 mg q. 6 h or 1 g q. 12 h. For uncomplicated urinary tract infections: 500 mg q. 12 h; for more serious UTI, including prostatitis, 500 mg q. 6 h or 1 g q. 12 h. Severe or chronic infections may require larger doses (up to 1 g q. 6 h). For dosage recommendations in patients with impaired renal function, consult package insert.

Children over 9 months of age — 25 to 50 mg/kg/day in equally divided doses q. 6 or 12 h. For otitis media due to *H. influenzae*: 75 to 100 mg/kg/day in equally divided doses q. 6 or 12 h but not to exceed 4 g/day. Dosage for children should not exceed dosage recommended for adults. There are no adequate data available on efficacy of b.i.d. regimens in children under 9 months of age.

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Inside Med-Chi

Med-Chi's Diligent Ghost

Is Med-Chi haunted? In my ten-plus years of association with the Faculty, there have been occasional references to a Med-Chi ghost. I myself have experienced phenomena that have led Faculty staff to postulate the existence of this ghost. When I first came to the Faculty in November 1971, the library employed several part-time students to work in the four floors of bookstacks. These students told stories of hearing footsteps on the cast-iron stairs, but no one ever appeared. At other times, these employees heard books being placed on shelves and book trucks being wheeled through the stacks when they knew they were alone. Sometimes a student would express reservations about having to work alone in the stacks, but most of them got used to and accepted the fact that periodically there were strange or suspicious noises in the library stacks.

Long before my arrival at Med-Chi, this "ghost" had been given the name Marcia. Shortly after I began work here, an aide, coming from the library stack door, said to me, "Marcia's shelving a lot of books up there today." I had thought I knew all the library employees. So I asked who Marcia was and learned that she had been a librarian who had lived and died in the building a long time ago.

My aquaintance with Marcia developed slowly. I, too, heard strange noises in the stacks, sometimes when alone, but often enough in the presence of other employees who also heard them. I came to accept this, especially after trying in vain a few times to find the source of the noises. I considered myself too sophisticated to believe in Marcia, but the name became a convenient way of referring to the phenomena.

About 1977, after I became Director of the Faculty library, I began to spend quite a bit of time alone in the Faculty building on nights and weekends, trying to catch up on my work. I quickly learned that Marcia's presence was not confined to the library stacks. My office is on the second floor of the building. The four floors of the Faculty building are connected by a beautiful winding marble stairway. It became common for me to hear the sound of footsteps going up or down this stairway, often followed or preceded by the sound of a door opening and closing.

In the beginning, I always investigated but never saw anything. One particular Saturday morning, I was absolutely convinced that I heard the front door of our building slam. I went down to investigate and saw nothing. I had no sooner gotten back to my desk than I heard the familiar footsteps on the stairs. I began to count them. As usual, the sounds went past the library door and continued up the stairs. After a while, I heard the fourth floor door at the top of the stairs open and close. I got up again, went to the bottom of the stairs, and then climbed the steps all the way to the fourth floor—counting. There was no doubt in my mind that my first count would correspond, and it did. There was no sign of life on the fourth floor. I shrugged my shoulders and went back to work.

A year or so later, I was working late one evening with another Faculty employee. When the other person stopped in and said he was getting ready to go, I decided I too had been there long enough that day. He then offered to stay to help close the building. Med-Chi is quite large, and it takes several minutes to go through the building turning out lights, shutting doors, turning off the elevator at the right floors, shutting down the heating or air conditioning systems, and setting the burgler alarms. It is much easier with two people, one working down from the fourth floor, and one working up from the basement. Once the burglar alarm is set, it is essential that both people leave simultaneously.

On this occasion, the two of us left and closed the door behind us as usual. We had just reached the bottom of the steps to the back parking lot when the door behind us opened and slammed shut. We turned around, startled, but there was nothing there. We waited a short while, reasoning that if the door really did open and shut, the silent alarm would have been set off, bringing the police. We could not go back in to check without setting off the alarm. After several minutes, it was obvious the alarm had not sounded.

With time, I and other long-term Med-Chi employees have come to accept Marcia or at least to take her for granted. I do not believe in her, but I am not at all surprised when a new employee returns from our library stack and says there is someone walking around there making strange noises.

• • •

This story would not be complete without an account of the real Marcia who was a Faculty employee for almost fifty years. She was the driving force behind the funding, design, and construction of the present Faculty building, and lived on the fourth floor of this building for thirty-seven years. Her funeral service was conducted in Osler Hall.

There really was a Marcia, and if her ghost does not occupy the Faculty building, it ought to. Marcia Crocker Noyes came to the Faculty as Librarian in November 1896 at age twenty-seven. She was a graduate of what is now Hunter College in New York. Miss Noyes often joked that her only qualification for the job was her ability to fill the requirement that she live in the library and be on call twenty-four hours a day. She was being slightly modest, since she had completed an internship

Public Relations Committee
James E. Bell MD, Chairman



Marcia Noyes, 1945

at the Enoch Pratt Library and was employed there as Supervisor of Stock Taking and Cataloging for Branching Libraries.

The hiring of a resident librarian for the Faculty was the result of prodding from William Osler MD, professor of medicine at the new Johns Hopkins Medical School. The great Dr. Osler had come to Baltimore from Philadelphia where he had become used to the magnificent College of Physicians Library. To his dismay, the Faculty Library in Baltimore had been allowed to deteriorate from its earlier greatness. At that time, the Library consisted of 7,000 outdated volumes stored in cartons. Dr. Osler joined with other prominent physicians to encourage the Faculty to purchase its own building for a meeting hall and a library. With time, the Faculty found funds to purchase a building at 847 Eutaw Street and to pay $25 a month for a librarian to live there.

The first librarian, Miss C. F. Parsons lasted a year and did not seem to accomplish much. After she departed, Dr. Osler asked his good friend and fellow physician, Dr. Bernard Steiner, the Head Librarian at the Enoch Pratt Library, to help the Faculty find a suitable librarian. Dr. Steiner responded that he had just the person for the job.

Marcia Noyes was interviewed by Dr. Osler on behalf of the Library Committee and by Dr. G. Lane Taneyhill on behalf of the Faculty's House Committee. She was immediately hired. In Miss Noye's own words, "In less than two weeks after I first heard about the Maryland Medical Society, I was living on the top floor, on duty twenty-four hours a day, and training myself for my job by doing it."

The new librarian found the library in total disarray. The boxed books were in no particular order. There were no shelves to put them on and no budget for supplies. Even worse was the attitude of most of her physican employers. In 1896, there were strong social prejudices against the single, young female. Professional recognition and courtesy from most physicians was out of the question. The alienation made it unlikely that physicians would even consider coming to the new librarian with medical reference questions. That Marcia Noyes succeeded in breaking down this prejudice and alienation was a credit to what she termed her "hard-boiled" nature. She made it a point to attend every Faculty function. She proved resourceful in borrowing (and when necessary, begging) furnishings and shelving. She also courted the friendship of wealthy physicians and encouraged them to make donations and bequests to the Faculty.

The location on Eutaw street soon proved inadequate for both the expanding Faculty activities and the library. With Dr. Osler's support, Noyes prodded the doctors into a building campaign. A lot was purchased at 1211 Cathedral St., and an elaborate building modeled on medical society libraries in Philadelphia, New York, and Boston was envisioned.

Marcia Noyes had her hand in every phase of the process from design through construction. Physicians visiting the construction site often would find the dainty and demure Miss Noyes climbing among the forms and inspecting the progress. Every detail of the work had to be completed according to her specifications.

When the building was completed and dedicated in 1909, it was the envy of every medical society. A special feature of the building was a rooftop apartment and garden for Noyes, her maid, and her two pet chows. Years later, *The Evening Sun* identified this as the "first penthouse in Baltmore."

In 1904, the Faculty reorganized its structure according to the AMA's new guidelines for state medical societies. At this time, Marcia Noyes was named Faculty Secretary. In 1925, her title was changed to Executive Secretary, again following AMA guidelines. In addition to managing the library and supervising the Faculty's growing staff, Noyes's duties included everything from planning for the Faculty's annual meetings to dealing with politicians and the press.

Marcia Noyes continued to guide the Faculty's growth into a modern medical society through April 1946. At that time several physicians recognized that with her failing health, Miss Noyes might not survive until the gala fiftieth anniversary of employment they were planning for her the following November. Acting probably for the first time against the adamant wishes

of Marcia Noyes, Faculty physicians gathered on April 24 for a special dinner in tribute to their Executive Secretary and Librarian. The physician's concern that this celebration be held while Noyes could still enjoy it proved timely. However, the strong-willed Marcia Noyes managed to hang on to life until November 24, a few days beyond the fiftieth anniversary of the day Dr. Osler brought her to the Faculty. Her funeral was conducted in the faculty's Osler Hall, with sixty of Med-Chi's physicians serving as honorary pallbearers.

If there is a ghost at Med-Chi, I have no doubt that it is Marcia Noyes. Her spirit is certainly not a bad one to have around, and no one could possibly deny her right to be here. She is probably overseeing the Faculty's affairs just as she always did.

JOSEPH E. JENSEN
Faculty Librarian

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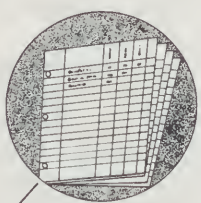
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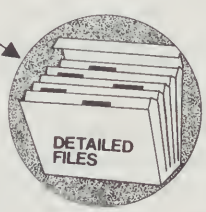
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Auxiliary

Over many years two of the most important projects of the Southern Medical Association's Auxiliary have been Doctor's Day, March 30, to honor physicians' contributions to humanity, and the Research and Romance of Medicine, which is devoted to the contributions of physicians and the healing arts to society throughout our history.

Traditionally AMA Auxiliaries in the southern states have been involved in these two areas. Most, if not all, of Maryland's counties participate in some sort of Doctors' Day celebration. The state auxiliary contributes a Research and Romance of Medicine exhibit at each of the Annual Conventions of the Southern Auxiliary.

This year Nancy Howell of Charles County will contribute for our Auxiliary the following information concerning Dr. Mudd. Nancy has interviewed the Mudd family and consulted research material in developing the following essay.

• • •

Dr. Samuel A. Mudd: Physician or Traitor?

On April 14, 1865, John Wilkes Booth assassinated Abraham Lincoln and, in doing so, touched off events that are still being debated today: the innocence or guilt of Dr. Samuel A. Mudd.

After the assassination, Booth leapt to the stage of Ford's Theater and fractured his leg. He got on his horse, left in the alley, and met one of the co-conspirators across the bridge in an area of Washington, D.C. called Anacostia. From there the two traveled to Surrattsville where they picked up whiskey and weapons at Mary Surratt's Tavern. By this time, Booth's leg was causing a fair degree of pain, and a decision to seek medical help was made.

Five months before, on November 20, 1864, Booth had been visiting another Charles Countian, John Thompson. Thompson and his father-in-law, Dr. William Queen, introduced Booth to Dr. Mudd after Mass at St. Mary's Church in Bryantown. Booth told these people that he was looking for land in the area for a friend of his and would appreciate their help. He also requested information on fast horses. Dr. Mudd said that a neighbor of his, Squire Gardner had horses and if Booth would come up later in the evening he would introduce them. Booth spent the night at Dr. Mudd's, bought an old, but fast, one-eyed horse from George Gardner, and left.

Therefore, when Booth needed medical attention and was headed for Port Tobacco (also in Charles County), it was only reasonable that he would go to Dr. Mudd's. For some, this may sound like a prearranged meeting. After all, wasn't Booth a friend of Dr. Queen's son-in-law? Why didn't he go there? Anyone familiar with the Charles County area would understand that the Mudd home would be the first he would come to on the way from Washington. Also, Dr. Queen lived closer to the town of Bryantown, and with 20,000 Union troops stationed in the County, it was more than likely some of them would have been stationed there.

Booth and David Herold arrived at the Mudd house around 4 A.M. Herold did the talking for the two and introduced them as Tyson (Booth) and Tyler (Herold). He said that Tyson had fallen from his horse and broken his leg. Dr. Mudd helped Herold get the injured Booth into the front parlor and then up to the front bedroom where he cut off the boot and splinted the leg.

According to Dr. Mudd's statement made the week following these events, "I found there was a straight fracture of the tibia about two inches above the ankle, . . . did not find the adjoining bone fractured. . . . I do not regard it a particularly painful or dangerous wound; there was nothing resembling a compound fracture."

It is also interesting and important to note that Booth, being an actor, had disguised himself with a false beard and moustache. In fact, later in the morning, Herold asked for a razor so that his friend might shave and hopefully feel better. Dr. Mudd noted in his statement that it seemed that the injured man had already lost his moustache earlier when Dr. Mudd came up to check on him.

Dr. Mudd left before noon to make his rounds and returned around 5 P.M. Upon arriving home, he noticed the two men were already on their horses and ready to leave. Herold asked directions to Parson Wilmer's at Piney Church. Mudd gave two different ways, one by public road and the other a short cut through Zekiah Swamp. The two took the shortcut.

On Easter Sunday, April 16, Dr. Mudd attended Mass at St. Peter's in Waldorf, and at that time heard of the assassination of President Lincoln. Dr. Mudd told his cousin, Dr. George Mudd of the two night visitors and asked his cousin to relay this information to the Union officers when he returned to Bryantown. George Mudd did not return to Bryantown until Monday. He reported his cousin's story to Lieutenant Dana. The following day, federal officers arrived to question Samuel Mudd. They left, returned on April 21, and surrounded the Mudd home with federal soldiers. Mrs. Mudd sent the house girl upstairs, and she returned with the boot that had been found under the bed. Inside was written "J.

Auxiliary to the Medical and Chirurgical Faculty of the State of Maryland. Mrs. Mildred S. Taylor, President; Mrs. Barbara M. Mayle, Editor.

Wilkes ——." Dr. Mudd was arrested on April 24, 1865, and was taken to what is now Fort McNair, Virginia. He was allowed no visitors, and no lawyers were allowed to see the accused. Booth was captured on April 26 in Virginia. The "conspirators" trial began on May 10 and recessed on June 14. The sentencing was June 29. Dr. Mudd escaped the death sentence by one vote.

Dr. Mudd arrived in the Dry Tortugas at Fort Jefferson Prison on July 24, 1865. In August 1867, one of the garrison officers returned from Havana bringing with him yellow fever. In a matter of weeks, the post physician and most of the officers had died in the epidemic. Dr. Mudd became not only the post physician but also the commander. There were 400 on the island; 300 came down with the fever, and 40 died. The epidemic lasted 47 days. A petition, signed by prisoners, soldiers, and officers, was sent to President Johnson asking for Mudd's release. The petition never reached the President.

Dr. Mudd was pardoned on February 14, 1869, and returned home on March 20. He died on January 10, 1883 of pneumonia contracted while making night calls on his patients. He had celebrated his 59th birthday on December 20.

The events surrounding the assassination as they concern Dr. Mudd present many questions. Did the meeting in November 1864 constitute conspiracy? If that were the case, anyone could be accused of conspiring to commit a crime because one might have had a chance meeting with a person who might commit a crime. Is it a conspiracy to treat a broken leg at 4 A.M. Saturday morning? If so, let's check out those hospital emergency rooms. We've all seen more than a few broken bones at that time of the morning. Are we then to suspect a crime?

What about both men having guns when they came to the Mudd home? In the 1800s, most men did carry guns and rifles, especially as this was wartime and there were many soldiers who had deserted and were returning to their homes. Both they and civilians carried guns for protection. Back then it would have been odd NOT to have a gun.

Why did Mudd delay in notifying the authorities of his night visitors? What reason was there to notify them? Is every broken leg to be reported? Mudd had no way of knowing that anything was amiss. Those who have grown up with radio, television, and telephones forget that fast communication is a recent event. Even though the telegraph was in use at the time of the Lincoln assassination, Bryantown was not big enough to have this service. Even if it had, Dr. Mudd lived approximately 10 miles from the town, and unless someone who had heard the news had gone by Dr. Mudd's there still would have been no way for him to have known about the crime. Once he did hear, on Easter Sunday, he asked his cousin, George, who lived in Bryantown to tell the authorities. Unfortunately, George did not return to his home until the next day, and those same authorities did not see fit to talk to Dr. Mudd until Tuesday.

Probably the most upsetting aspect of this ordeal is the fact that Dr. Mudd and the others were tried by a military court. This military commission was illegal, and according to the Supreme Court in 1866, the commission had no jurisdiction if the authority of the United States is unopposed and the civil court system is in operation. Dr. Mudd was allowed no lawyer and was not allowed to speak in his own defense or present any witnesses or evidence. Hardly the things this country has stood for.

During the days that followed the assassination, many people were looking for a fast answer to a national tragedy. Southern Maryland was known for its pro-Confederacy stand (remember the 20,000 Union troops). Many feel it was a form of punishment; an attack on one of the prominent families. Others feel the conviction and sentencing were just.

I spent the day with Dr. Mudd's granddaughter, Louise Mudd Arehart. Her home is full of Civil War memorabilia and Mudd family scrap books. She has been working for her grandfather's pardon and the restoration of the original home since the late 1960s. It is the hope of the Dr. Mudd Society to have a library to house these collections and to serve as a resource center for Civil War scholars. Should anyone wish more information on the Society or wish to become involved in any way, please contact Mrs. Arehart or me. You will find this a fascinating and absorbing subject. I wonder if the same thing could happen again?

NANCY H. HOWELL
Councilor, Southern Medical Association Auxiliary

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The Library Page

Faculty Begins Access to AMA's Medical Information Network

On February 1, 1985 the Faculty began using another computerized database in addition to the ones available through the National Library of Medicine and the bibliographic Retrieval Service. This new service was jointly developed by the American Medical Association and the GTE Telenet Communications Corporation. It is known as MINET (AMA/GTE Medical Information Network).

MINET offers two additional features not previously available in the existing computerized databases accessed by the Faculty. With MINET, direct information regarding a particular drug or disease can be found on the computer terminal. Also, MINET offers an electronic mail service that allows communication between subscribers to this service.

Currently, seven files make up the MINET system. Six are medical data bases produced by the AMA and licensed to GTE, and the seventh file is the electronic mail service.

The Disease Information Base contains information on more than 3,500 identifiable diseases. It is produced by the AMA's Division of Drugs and Technology. This file gives information on the diseases' nomenclature, etiology, signs and symptoms, laboratory findings, radiological findings, disease course, and pathological findings.

Information can be retrieved by typing in either the disease name or an alternate term to describe the disease. For example, entering SIDS on this file would draw up the disease name: SUDDEN INFANT DEATH SYNDROME. Entering the command for information on pathological findings, for example, would produce the following:

Disease Name:	SUDDEN INFANT DEATH SYNDROME
Pathological Findings:	Variable; petechiae in thoracic organs; lungs emphysematous; pulmonary congestion, edema; inflammatory changes in lungs; pulmonary arterial muscle mass increased; thymus large; lymph nodes prominent throughout body.

The Drug Information Base also is produced by the AMA's Division of Drugs and Technology. It contains information on more than 1,100 individual drugs marketed under some 5,000 trade names in the United States, Canada, and Mexico. Each entry contains information regarding nomenclature, uses, actions, pharmacokinetics, adverse reactions, toxicity, precautions, interactions, dosages and administration, preparations, a summary, and references. In addition, some contain patient medication instructions.

Medical and Chirurgical Faculty of the State of Maryland Library, 1211 Cathedral Street, Baltimore, MD 21201. Joseph E. Jensen, Librarian.

This file can be accessed in several different ways. The generic or trade name can be used to gather information on a drug, or the file can be entered by a particular disease. The latter approach lists the drugs used for therapy. For example, information on topical acyclovir, which is used to treat herpes genitalis, can be found by asking the computer for the drug name acyclovir or for drugs used to treat herpes. A summary for the drug would be as follows:

Topic—Summary:	ACYCLOVIR (TOPICAL) (0793)
Synopsis:	Acyclovir is an antiviral drug used for the management of initial herpes genitalis and mucocutaneous herpes simplex virus infections in immunocompromised patients. It is a nucleoside analogue of guanosine and is probably the best example of an metabolite with selective antiviral activity. In herpesvirus-infected cells only, acyclovir is phosphorylated by viral-encoded thymidine kinase to the monophosphate. The monophosphate derivative is then further phosphorylated by host enzymes to the triphosphate, which then act as preferential inhibitors of viral DNA polymerase. As a result of this unique action, acyclovir has potent antiviral activity with limited host toxicity. Mild local reactions constitute the only common adverse effect.

The Socio/Economic Bibliographic Information Base is a database produced by the AMA's Division of Library and Archival Services. This file is similar to the one the Faculty has produced for its membership over the years. Its distinguishing feature is references to nonclinical aspects of the health care field. This file scans more than 700 journals for articles related to economics, ethics, legislation, statistics, and any other area that might be of interest to a person in the health care field. Citations contain the author, title, and source journal but not an abstract. The file can be searched by author, title word, or subject.

The Excerpta Medica Physicians Information Retrieval and Education Service (EMPIRES) is a file that acts as a compliment to the Socio/Economic file. EMPIRES indexes the various articles recently published in over 300 different medical journals. These journals are the most prestigious in medical specialties. Although it is not as comprehensive as the MEDLARS file of the National Library of Medicine, it is a useful tool to gather several articles quickly. Many of the articles indexed appear with the author's abstract.

The Medical Procedure Coding and Nomenclature Information File is another product of the AMA's Division of Drugs and Technology. It is the electronic version of the CPT system used to report medical services and procedures. It contains more than 6,000 descriptions that can be retrieved by entering the procedure's name, code, or a section's heading.

The final set of AMA-sponsored files is devoted to continuing medical education. This file was developed at the Massachusetts General Hospital. It gives physicians an opportunity to earn Category I CME credits towards the AMA's Physician's Recognition Award. This file contains computer-simulated case-oriented programs. The self-paced learning course can be geared to any of 21 current programs. They cover such areas as abdominal pain, arrythmias, coma, hypertension management, joint pain, and meningitis.

The other service offered is MED/MAIL. Using computer terminal, subscribers to the system send and receive messages 24 hours a day anywhere in the United States. Other special features include two electronic bulletin boards. One contains CME information, and the other has meeting information maintained by the American Medical Association.

This brief description of the AMA/GTE system lists only some of its features. For more complete information, visit the library at the Faculty for a demonstration. Physicians who have personal computers may want to contact the Faculty Librarian for additional information in accessing this system for their own practice.

ADAM SZCZEPANIAK
Associate Librarian

Selected Medical Literature Searches

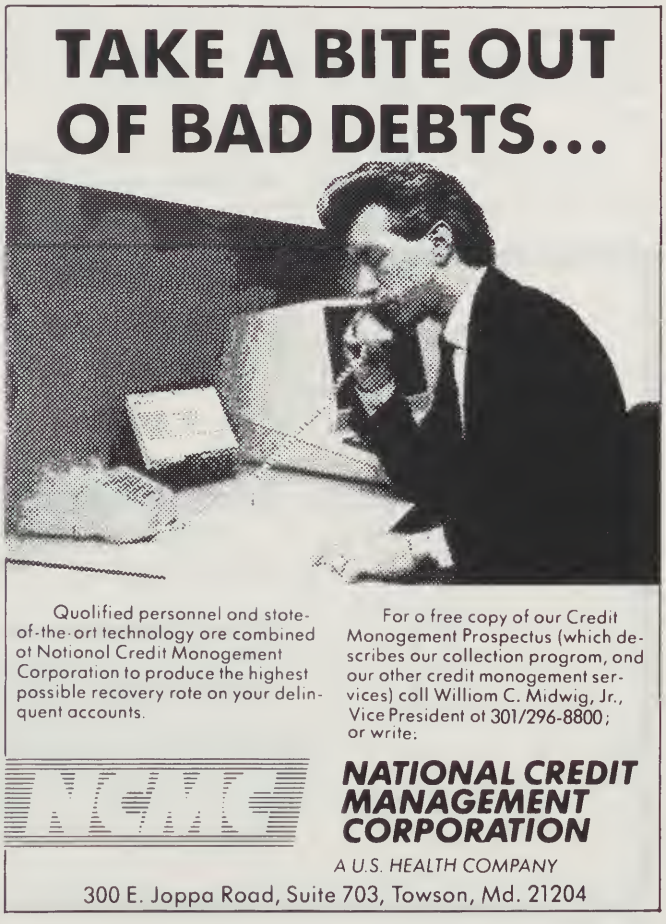
The following are among the computerized medical literature searches provided to Med-Chi members during December 1984.

	No. of Citations
1. Adverse effects of hepatitis B vaccine	31
2. Chemically induced alopecia	27
3. Dysgeusia	12
4. Heat injuries and heat exhaustion	26
5. Hip prosthesis and infection	32
6. Osteoporosis therapy	39
7. Preleukemia	16
8. Shoulder dystocia	12
9. Treatment of aphthous stomatitis	24
10. Utilization and complications of coronary angiography	23

If you would like a copy of one of these searches or a search run on any biomedical topic, call or write the library.

SUSAN E. HARMAN
Reference and Circulation Librarian





Maryland Oncology Newsletter

Screening and Early Detection for Adenocarcinoma of the Large Bowel

In Maryland this year over 2,500 patients will be diagnosed to have adenocarcinoma of the large bowel, and it is estimated that over 1,000 patients will die of this disease in the same period. The impact of this disease is real, not only in the state of Maryland but also throughout the United States and the western hemisphere. Surgery remains the most effective method of treatment. The patient survival depends on the *stage*, that is, extent of the disease at the time of diagnosis, and on the *surgical approach* and management of the primary tumor.

Early detection plays a major role. It has been shown that asymptomatic patients diagnosed on routine physical examination to harbor the disease have the best survival rates: 88 percent or better. Thus, it is clear that screening for early diagnosis is an important factor.

Patients with carcinomas that are confined in the bowel wall (that is, Dukes A) have an 80 percent five-year survival, while patients with tumors that penetrated through the bowel wall (Dukes B) have a 40 to 50 percent five-year survival, if regional lymph nodes are not involved. On the other hand, patients who have the regional lymph nodes involved by tumor (Dukes C) have a survival rate of 20 percent, while patients with distant metastases have less than 1 percent survival rates.

If you have questions, please write or call the Surgical Oncology Program at the University of Maryland Medical System, Room N13E02, Baltimore, MD 21201 (301-528-5224).

All physical examinations should include rectal examination for masses or gross evidence of blood. The rectal contents also should be tested for occult blood, an effective method of screening, although there is a high yield of false-positive and false-negative results. While the false-negative results may be corrected by repeat testing, the false-positive results can be improved by placing the patient on a diet free of meat and Vitamin C for three days. However bleeding hemorrhoids must undergo large bowel investigation prior to hemorrhoidectomy.

It is highly recommended that all persons age 40 and over have a digital rectal examination annually with stool exams for occult blood. At age 50, a sigmoidoscopy and preferably a colonoscopy should be performed every 3 to 5 years. However, patients who are a high-risk for developing large bowel cancer (such as familial polyposis, Gardner's syndrome, ulcerative colitis, history of polyps, prior colon cancer, and family history of cancer of the colon or rectum) should receive more frequent and intensive examinations beginning at an earlier age. If any of these tests are positive or if the clinical symptoms (such as abdominal pain, change in bowel habits, or bloated feeling) warrant further investigation, a barium enema, with and without air contrast and or colonoscopy are in order.

E. GEORGE ELIAS MD
University of Maryland, Surgical Oncology Program

. . . in the April issue of MMJ . . .

Use and Abuse of Cimetidine in a Gastroenterology Clinic

Occult Hemorrhage in a Neonate with Hemophilia A

Endoscopic Sclerotherapy of Esophageal Varices

One Minute with Diabetes

A significant number of type II diabetics (maturity onset) are overweight. In fact, there are those whose weight exceeds the 300-pound limit of the standard physician's office sale, and therefore cannot be weighed in the usual manner. It would be helpful if these patients could be weighed without the need of taking them to the railroad station to weigh on a freight scale.

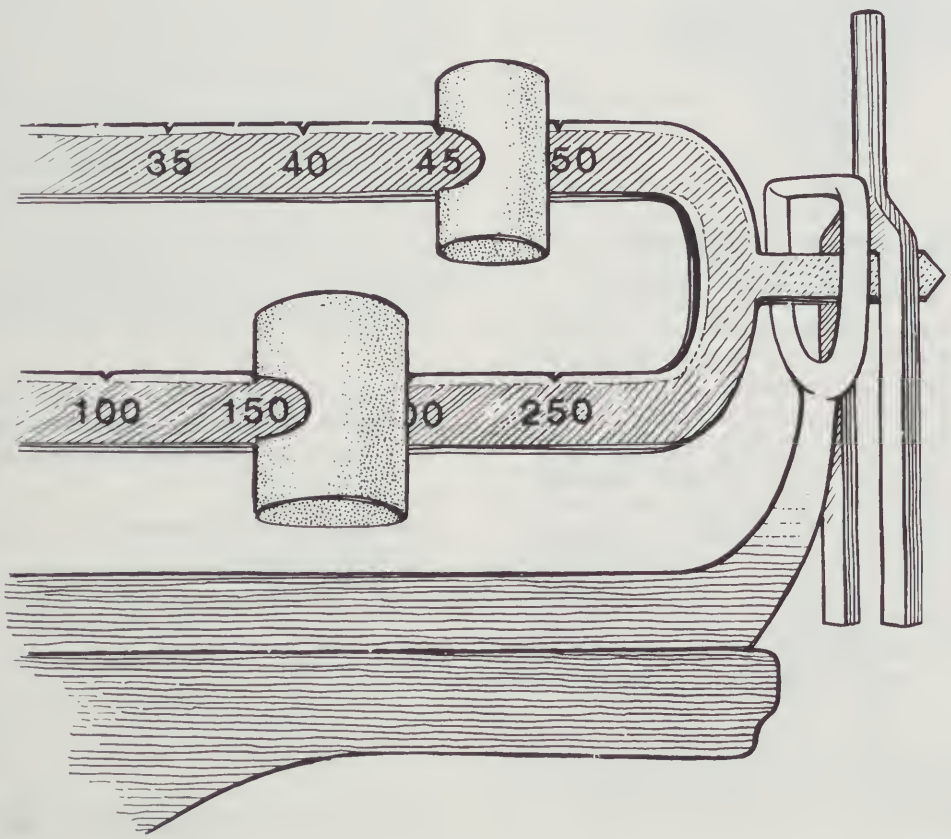
There are two recommended methods for weighing them in the physician's office. The first involves placing two standard physician's scales side by side and having the patient stand with one foot on each scale. The weight for the individual is then the sum of the two scale weights. For example, 175 pounds on each scale would show that the patient weighed 350 pounds.

Since not very many physicians have two scales in their offices, there is a second technique for weighing the individual who exceeds 300 pounds. First, a normal-size person is weighed on the office scale. Let us assume that this person weighs 205 pounds. Then a tuning fork or other convenient object is placed on the tip of the beam of the scale, and the same person is reweighed, yielding a weight of, for example, 55 pounds. This would mean that the added object (tuning fork) made a difference of 150 pounds.

Now, if we return to our overweight patient and weigh him or her on the scale with the tuning fork in place, the scale will show 195 pounds. (Figure). By adding the 150-pound correction to the 195 pounds, we are able to determine that the true weight of the patient is 345 pounds.

This useful system permits physicians to weigh almost any patient in their offices without the inconvenience of expensive equipment.

DEWITT E. DELAWTER MD



HBP Commentary

Research at the National Institute on Aging in Behavioral Training for High Blood Pressure Control

Two behavioral treatments—systolic blood pressure biofeedback and relaxation—are purported to be effective in the control of high blood pressure, but until recently evidence has been insufficient to warrant that conclusion. However, researchers in Baltimore have provided data supporting the effectiveness of these nonpharmacologic treatments.

Nonpharmacologic therapy for high blood pressure is recommended in the 1984 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (JNC III) both as a definitive intervention and as an adjunct to drug therapy, as previously described in this *Journal.*[1] Among the types of nonpharmacologic treatment now being studied extensively are blood pressure biofeedback and relaxation training. Researchers at the Gerontology Research Center in Baltimore, part of National Institute on Aging (NIA), are showing that such behavioral training can be an alternative to drug use for some patients with mild hypertension (diastolic pressures ≥90 and ≤105 mm Hg).[2]

Bernard T. Engel PhD, Michael S. Glasgow PhD, and Kenneth R. Gaarder MD have tested three behavioral techniques: daily self-monitoring of blood pressure, relaxation training, and biofeedback.[3] Biofeedback is a process in which patients use a blood pressure cuff to get signals, or feedback, from brachial artery sounds. The study was designed to evaluate the effectiveness of "relaxation" and systolic blood pressure "biofeedback." One hundred twenty-seven volunteers whose average diastolic blood pressures in doctors' offices were at least 90 mm Hg were enrolled. Investigators first tested the feasibility of having these people monitor their own blood pressures. The volunteers learned to use sphygmomanometers and monitored their own blood pressures three times a day for one month. Once a week, their blood pressures were measured by a health professional. At the end of the month, each patient reviewed the measurements with one of the investigators.

About half the patients were receiving no antihypertensive drugs and half were taking only diuretics. This stage of the study showed that patients could successfully monitor their own blood pressures and report the results. In addition, these patients achieved significant reductions in blood pressures.

The baseline findings showed: (1) extensive self-monitoring of blood pressure is feasible and practical; it is also in itself a powerful technique for lowering blood pressure; (2) systolic pressure rises throughout the day but peaks in the afternoon; (3) diastolic pressure falls from morning to evening but peaks in the afternoon; (4) intradaily range of systolic but not diastolic blood pressure is higher among women than among men; (5) both systolic and diastolic pressures fall throughout the first three weeks of monitoring (−5.7 mm Hg and −4.2 mm Hg, respectively).

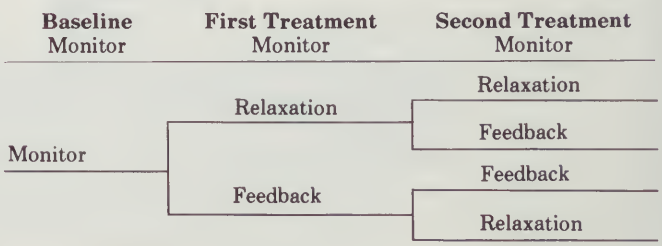
Patients who completed the initial stage of the study were assigned to groups for biofeedback or relaxation training or to a control group that continued self-monitoring.[4] Those using biofeedback and relaxation took their pressures before and after practicing the techniques. A crossover design was employed: after three months, half the patients in each training group learned to use the other technique (Figure).

Patients practicing biofeedback learned to inflate and keep the cuff of the sphygmomanometer at about systolic pressure while listening to and trying to inhibit artery sounds. When they succeeded in reducing systolic pressure, the sounds disappeared. They practiced this technique several times daily, especially at the times of day when previous measurements had shown their pressures to be highest, generally in the afternoons. During training they learned to recognize the subjective feelings of relaxation associated with successful lowering of blood pressure and to practice eliciting these feelings at convenient times.

Acute and sustained effects of relaxation and systolic blood pressure feedback were then studied. Data from two three-month treatment periods were compared with results from the one-month baseline period; control and treatment groups also were compared. Ninety borderline hypertensive patients completed the treatments.

In the short term, both the biofeedback and relaxation techniques lowered blood pressures significantly as

Figure. Study Design: 1-month Baseline and Two 3-month Treatment Phases.



HBP Commentary is contributed by the Maryland High Blood Pressure Commission. Editors: R. Patterson Russell MD, Past Chairman; Donald O. Fedder PharmBS, DrPH, Chairman; and Carol Lewis MPH, ScD, Executive Director.

the patients developed their skills. Improvements were noted in patients using diuretics as well as in those taking no medications; however, the techniques appeared to be more effective for those not on antihypertensive medication.

Long-term effects included a decline in BP for at least six months with regular monitoring. The greatest lowering of BP by behavioral intervention occurred during the daily time periods when pressures tended to be highest. The long-term effects of biofeedback were slightly greater than those of relaxation, and a combination of relaxation and biofeedback was more effective than either used alone (Table).

Follow-up studies have shown that these reductions in blood pressure could be maintained for at least 18 months.[5] About one-third of the patients receiving diuretic therapy had their medications discontinued by their physicians, and they were able to maintain reduced blood pressure for at least nine months following discontinuation of medications. Having shown behavioral methods to be successful in reducing mild hypertension, the researchers are now testing the effectiveness of these techniques on persons who have more severe high blood pressure. They have developed a model for a behavioral stepped-care treatment (which begins with daily blood pressure monitoring) and are experiencing positive results. However, the researchers point out that behavioral methods for treating hypertension have yet to be subjected to the kind of large-scale clinical trials to which pharmacologic treatments are subjected before being advocated for widespread use.

The Biofeedback Certification Institute of America (4301 Owens St., Wheat Ridge, CO 80033) keeps a list of clinicians who use behavioral techniques to control hypertension and other conditions in their patients. For regional information call Carol Lewis at the Maryland High Blood Pressure Commission (301-383-7263).

Table. Long-Term (>5 months) Effects of Treatment on Average Systolic and Diastolic Blood Pressure

Treatment Group	Changes in Average Afternoon Blood Pressures (SBP/DBP in mm Hg)* (N = 90)
Monitor	−7/−4
Relaxation only	−6/−4
Biofeedback only	−9/−8
Relaxation followed by biofeedback	−10/−6
Biofeedback followed by relaxation	−12/−10

* Changes from average pressures during 1-month baseline period.

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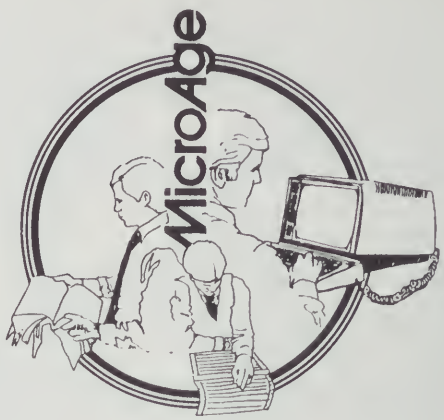
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Medical Miscellany

AMA's Survey and Opinion Briefs

Public Support for Malpractice Reform

In many parts of the U.S., issues related to physicians' professional liability are being hotly debated in political and legislative forums. Not since the so-called crisis of 1975 has so much attention been focused on the laws that govern the ways in which malpractice suits are adjudicated. Several states currently are considering proposals to reform liability statutes, and the public is becoming increasingly knowledgeable about this complex topic. It is likely that public opinion will weigh heavily in these deliberations.

For this reason, the AMA has included a series of questions on its annual public opinion survey to track key attitudes toward malpractice. We present these data and their implications for reform of the legal system as it relates to professional liability.

The following findings are based on telephone interviews with 1,503 randomly-selected U.S. adults. Interviews were conducted during the first week in July 1983.

As you no doubt know, there have been a lot of cases recently where people have sued doctors for malpractice. Do you think people who sue physicians for malpractice are usually justified in bringing suit, or are they just looking for an easy way to make some money?

	Percent 1982	Percent 1983
Usually justified in bringing suit	47	41
Just looking for easy way to make money	43	47
Not sure	10	12

As indicated, public opinion is very divided on this issue. A plurality now support the position that most malpractice suits are *not* justified. The six point decline in "justified" responses during the past year is statistically significant and may reflect a trend toward growing public skepticism about the validity of many liability suits. It is interesting to note that this view is most prevalent among the elderly (aged 65+), where only 26 percent believe most suits are justified.

Do you think the amount of money awarded to patients by juries in malpractice suits is usually too much, not enough, or about right?

	Percent 1982	Percent 1983
Too much	47	45
Not enough	7	7
About right	38	37
Not sure	8	11

This opinion appears to be quite stable in the time frame indicated. A plurality feel that current awards are too high; very few support the opposite viewpoint. This perception varies substantially by region as 58 percent of respondents in the West North Central states (Dakotas, Nebraska, Kansas, Missouri, Iowa, Minnesota) say that current awards are too high. Only 40 percent of those in New York, Pennsylvania and New Jersey agree with that position.

Do you think that there should be a limit on the amount of money that can be awarded to someone suing a doctor for malpractice?

	Percent 1982	Percent 1983
Yes	61	62
No	35	35
Not sure	4	3

Again, the pattern is one of stability with a sizable majority agreeing with the need for a limit on malpractice awards. As seen in the above findings, support for this reform is greatest among the elderly and among the residents of the West North Central region.

The survey also measured views toward a series of proposed changes in the medical system to help contain rising costs. The most popular proposal and the only one receiving a majority of support is "You would accept limits on the amount that you could sue your doctor for malpractice." 55 percent approve of this proposed change. This is in sharp contrast to the 22 percent who last year agreed that "You would give up the right to sue for possible malpractice." This is clearly a critical distinction in public support for liability reform.

Summary

In combination, these findings indicate that a majority of the American public is now ready to accept reform of the medical malpractice system. Views toward more complex proposals could not be measured because of comprehension problems. However, the basic views that:

- most suits are unjustified
- awards are too high, and
- an award limit is needed

suggest that changes appealing to these fundamental concerns will be positively received.

If you have any questions or want further information, contact Larry Freshnock PhD (312-751-6452).

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1. Strauss WE, McIntyre KM, Parisi AF, et al: Safety and efficacy of diltiazem hydrochloride for the treatment of stable angina pectoris: Report of a cooperative clinical trial. Am J Cardiol 49:560-566, 1982.
2. Pool PE, Seagren SC, Bonanno JA, et al: The treatment of exercise-inducible chronic stable angina with diltiazem: Effect on treadmill exercise. Chest 78 (July suppl):234-238, 1980.

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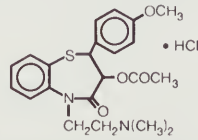
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DESCRIPTION

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Diltiazem hydrochloride is a white to off-white crystalline powder with a bitter taste. It is soluble in water, methanol, and chloroform. It has a molecular weight of 450.98. Each tablet of CARDIZEM contains either 30 mg or 60 mg diltiazem hydrochloride for oral administration.

CLINICAL PHARMACOLOGY

The therapeutic benefits achieved with CARDIZEM are believed to be related to its ability to inhibit the influx of calcium ions during membrane depolarization of cardiac and vascular smooth muscle.

Mechanisms of Action. Although precise mechanisms of its antianginal actions are still being delineated, CARDIZEM is believed to act in the following ways:

1. Angina Due to Coronary Artery Spasm: CARDIZEM has been shown to be a potent dilator of coronary arteries both epicardial and subendocardial. Spontaneous and ergonovine-induced coronary artery spasm are inhibited by CARDIZEM.
2. Exertional Angina: CARDIZEM has been shown to produce increases in exercise tolerance, probably due to its ability to reduce myocardial oxygen demand. This is accomplished via reductions in heart rate and systemic blood pressure at submaximal and maximal exercise work loads.

In animal models, diltiazem interferes with the slow inward (depolarizing) current in excitable tissue. It causes excitation-contraction uncoupling in various myocardial tissues without changes in the configuration of the action potential. Diltiazem produces relaxation of coronary vascular smooth muscle and dilation of both large and small coronary arteries at drug levels which cause little or no negative inotropic effect. The resultant increases in coronary blood flow (epicardial and subendocardial) occur in ischemic and nonischemic models and are accompanied by dose-dependent decreases in systemic blood pressure and decreases in peripheral resistance.

Hemodynamic and Electrophysiologic Effects. Like other calcium antagonists, diltiazem decreases sinoatrial and atrioventricular conduction in isolated tissues and has a negative inotropic effect in isolated preparations. In the intact animal, prolongation of the AH interval can be seen at higher doses.

In man, diltiazem prevents spontaneous and ergonovine-provoked coronary artery spasm. It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure and, in exercise tolerance studies in patients with ischemic heart disease, reduces the heart rate-blood pressure product for any given work load. Studies to date, primarily in patients with good ventricular function, have not revealed evidence of a negative inotropic effect; cardiac output, ejection fraction, and left ventricular end diastolic pressure have not been affected. There are as yet few data on the interaction of diltiazem and beta-blockers. Resting heart rate is usually unchanged or slightly reduced by diltiazem.

Intravenous diltiazem in doses of 20 mg prolongs AH conduction time and AV node functional and effective refractory periods approximately 20%. In a study involving single oral doses of 300 mg of CARDIZEM in six normal volunteers, the average maximum PR prolongation was 14% with no instances of greater than first-degree AV block. Diltiazem-associated prolongation of the AH interval is not more pronounced in patients with first-degree heart block. In patients with sick sinus syndrome, diltiazem significantly prolongs sinus cycle length (up to 50% in some cases).

Chronic oral administration of CARDIZEM in doses of up to 240 mg/day has resulted in small increases in PR interval, but has not usually produced abnormal prolongation. There were, however, three instances of second-degree AV block and one instance of third-degree AV block in a group of 959 chronically treated patients.

Pharmacokinetics and Metabolism. Diltiazem is absorbed from the tablet formulation to about 80% of a reference capsule and is subject to an extensive first-pass effect, giving an absolute bioavailability (compared to intravenous dosing) of about 40%. CARDIZEM undergoes extensive hepatic metabolism in which 2% to 4% of the unchanged drug appears in the urine. In vitro binding studies show CARDIZEM is 70% to 80% bound to plasma proteins. Competitive ligand binding studies have also shown CARDIZEM binding is not altered by therapeutic concentrations of digoxin, hydrochlorothiazide, phenylbutazone, propranolol, salicylic acid, or warfarin. Single oral doses of 30 to 120 mg of CARDIZEM result in detectable plasma levels within 30 to 60 minutes and peak plasma levels two to three hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3.5 hours. Desacetyl diltiazem is also present in the plasma at levels of 10% to 20% of the parent drug and is 25% to 50% as potent a coronary vasodilator as diltiazem. Therapeutic blood levels of CARDIZEM appear to be in the range of 50 to 200 ng/ml. There is a departure from dose-linearity when single doses above 60 mg are given; a 120-mg dose gave blood levels three times that of the 60-mg dose. There is no information about the effect of renal or hepatic impairment on excretion or metabolism of diltiazem.

INDICATIONS AND USAGE

1. **Angina Pectoris Due to Coronary Artery Spasm.** CARDIZEM is indicated in the treatment of angina pectoris due to coronary artery spasm. CARDIZEM has been shown effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (resting angina with ST-segment elevation occurring during attacks).
2. **Chronic Stable Angina (Classic Effort-Associated Angina).** CARDIZEM is indicated in the management of chronic stable angina. CARDIZEM has been effective in controlled trials in reducing angina frequency and increasing exercise tolerance.

There are no controlled studies of the effectiveness of the concomitant use of diltiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities.

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

1. **Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
2. **Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
3. **Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
4. **Acute Hepatic Injury.** In rare instances, patients receiving CARDIZEM have exhibited reversible acute hepatic injury as evidenced by moderate to extreme elevations of liver enzymes. (See PRECAUTIONS and ADVERSE REACTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS).

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vitro bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outweigh its potential risks in this situation.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences, as well as their frequency of presentation, are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%), AV block (1.1%). In addition, the following events were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrence.

Cardiovascular:	Flushing, arrhythmia, hypotension, bradycardia, palpitations, congestive heart failure, syncope.
Nervous System:	Paresthesia, nervousness, somnolence, tremor, insomnia, hallucinations, and amnesia.
Gastrointestinal:	Constipation, dyspepsia, diarrhea, vomiting, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH.
Dermatologic:	Pruritus, petechiae, urticaria, photosensitivity.
Other:	Polyuria, nocturia.

The following additional experiences have been noted:

A patient with Prinzmetal's angina experiencing episodes of vasospastic angina developed periods of transient asymptomatic asystole approximately five hours after receiving a single 60-mg dose of CARDIZEM.

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: erythema multiforme; leukopenia; and extreme elevations of alkaline phosphatase, SGOT, SGPT, LDH, and CPK. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

OVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with oral diltiazem has been limited. Single oral doses of 300 mg of CARDIZEM have been well tolerated by healthy volunteers. In the event of overdosage or exaggerated response, appropriate supportive measures should be employed in addition to gastric lavage. The following measures may be considered:

Bradycardia	Administer atropine (0.60 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.
High-Degree AV Block	Treat as for bradycardia above. Fixed high-degree AV block should be treated with cardiac pacing.
Cardiac Failure	Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics.
Hypotension	Vasopressors (eg, dopamine or levarterenol bitartrate).

Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating physician.

The oral LD_{50}'s in mice and rats range from 415 to 740 mg/kg and from 560 to 810 mg/kg, respectively. The intravenous LD_{50}s in these species were 60 and 38 mg/kg, respectively. The oral LD_{50} in dogs is considered to be in excess of 50 mg/kg, while lethality was seen in monkeys at 360 mg/kg. The toxic dose in man is not known, but blood levels in excess of 800 ng/ml have not been associated with toxicity.

DOSAGE AND ADMINISTRATION

Exertional Angina Pectoris Due to Atherosclerotic Coronary Artery Disease or Angina Pectoris at Rest Due to Coronary Artery Spasm. Dosage must be adjusted to each patient's needs. Starting with 30 mg four times daily, before meals and at bedtime, dosage should be increased gradually (given in divided doses three or four times daily) at one- to two-day intervals until optimum response is obtained. Although individual patients may respond to any dosage level, the average optimum dosage range appears to be 180 to 240 mg/day. There are no available data concerning dosage requirements in patients with impaired renal or hepatic function. If the drug must be used in such patients, titration should be carried out with particular caution.

Concomitant Use With Other Antianginal Agents:

1. **Sublingual NTG** may be taken as required to abort acute anginal attacks during CARDIZEM therapy.
2. **Prophylactic Nitrate Therapy**—CARDIZEM may be safely coadministered with short- and long-acting nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.
3. **Beta-blockers.** (See WARNINGS and PRECAUTIONS.)

HOW SUPPLIED

Cardizem 30-mg tablets are supplied in bottles of 100 (NDC 0088-1771-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1771-49). Each green tablet is engraved with MARION on one side and 1771 engraved on the other. CARDIZEM 60-mg scored tablets are supplied in bottles of 100 (NDC 0088-1772-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1772-49). Each yellow tablet is engraved with MARION on one side and 1772 on the other.

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The tuberculosis sanitorium virtually has become medical history. In 1971, 20 states reported using only specialized tuberculosis hospitals for the care of TB patients. The number decreased to 17 states in 1973, and no states reported exclusive use of tuberculosis hospitals in 1980.[1] TB patients are treated on an ambulatory basis, and hospitalization of newly diagnosed cases is not necessary solely for infection containment.[2] The number of patients hospitalized for tuberculosis has declined from about 58,000 in 1960 to about 1,500 in 1981, an annual rate of decline of about 22 percent. However, the percentage of TB patients hospitalized has remained at 3 percent since 1974.[3]

Characteristics of Hospitalized TB Patients: Montebello Center, Maryland, 1981 to 1983

SUSAN M. BLAND MD; RANDY BERGER MD; JAMES P.G. FLYNN MD, MPH; and IRVING I. KESSLER MD, DrPH

Drs. Bland and Berger are residents, Department of Epidemiology and Preventive Medicine, University of Maryland School of Medicine. Dr. Flynn is Medical Director, Montebello Center. Dr. Kessler is Professor and Head of Department of Epidemiology and Preventive Medicine, University of Maryland School of Medicine.

Each year during the next several years, 25,000 new cases of tuberculosis probably will be reported in the United States. An estimated 1 out of 10 cases will require retreatment. Most treatment failures are due to irregularity or interruption of self-medication. Failure to comply with appropriate chemotherapy is the primary barrier to the control of TB in the United States.[4] In some large urban centers up to 60 percent of patients fail to successfully complete treatment.[5]

Although noncompliance is difficult to predict, experience has shown that the single, unemployed, inner-city alcoholic male is the most likely to be noncompliant. Approximately 23 to 31 percent of patients with newly diagnosed TB do not complete their chemotherapy within 24 months.[6]

A challenge to tuberculosis management has been how to treat the noncompliant patient. Approaches to noncompliance include supervised intermittent chemotherapy, shorter durations of therapy, and the use of fewer drugs.[7,8] The American Thoracic Society and Center for Disease Control officially endorsed short-course chemotherapy (9 to 12 months) in March 1981.[9] The combination of isoniazid (INH) and rifampin (RIF) has been shown to be effective in short-course chemotherapy. A substantial portion of this therapy may be given on a twice-weekly basis.[10]

Changes in the health care delivery system could increase compliance by making clinics more hospitable and encouraging good patient/professional relationships.[11] It is necessary for physicians to be aware of alternative therapeutic regimens that may be beneficial for the potentially noncompliant patient.[12]

Alcoholics make up the largest percentage of noncompliant TB patients. One study showed that half the alcoholics failed to complete 6 months of consecutive treatment.[13] Although the actual incidence of tuberculosis in the alcoholic population is unknown, a rate of 400 per 100,000 has been estimated. As the incidence of TB declines, it is likely that the proportion of patients who are alcoholics will increase.[14]

In managing noncompliant alcoholic TB patients the first step is to identify who they are before they become treatment failures. The brief MAST interview (a shortened version of the Michigan Alcoholism Screening Test) is an efficient screening tool that can be administered at an initial clinic visit.[15]

It has been recommended that alcoholics with a history of previous treatment for tuberculosis be hospitalized for the initiation of a new treatment regimen.[16] There have been successful attempts at ambulatory management using a supervised chemotherapy regimen.[17]

Heavy drinkers may have higher SGOT levels during therapy; however, there is not a greater incidence of progressive hepatotoxicity. Treatment and monitoring of drug toxicity should be done in all patients being treated with RIF and INH.[18] For the noncompliant alcoholic patient unable to tolerate rifampin, nonrifampin-containing intermittent regimens have been proved effective. However, the authors note that the cost effectiveness of rifampin regimens is superior.[19]

An interesting concept of homes for homeless TB alcoholics has been assessed in England. Selected patients were discharged from the hospital directly to a hostel where drinking in moderation is tolerated.[20] For the alcoholic TB patient, treatment of tuberculosis is primary and treatment of alcoholism secondary.

A Medline search was undertaken for tuberculosis and pulmonary tuberculosis cross-referenced with hospitalization and alcoholism. Titles of articles in English printed from 1972 through 1983 show that approximately half were published outside the United States, an indication that tuberculosis is not a major problem in our country at present. Titles of all relevant articles convey the impression that there is difficulty dealing with noncompliant alcoholic patients and that the advent of shorter courses of chemotherapy may be part of the solution. Other reasons for the hospitalization of patients with tuberculosis include: patients too sick for outpatient care, diagnostic difficulties, and treatment for another illness.[21]

Purpose

The purpose of this study was to develop a profile of the hospitalized TB patient in a nonacute care hospital. As new and more flexible regimens of treatment of tuberculosis evolved (such as short-course chemotherapy with increased emphasis on outpatient treatment), the proportion of TB cases requiring hospitalization declined. Consequently there has been a change in the characteristics of hospitalized tuberculosis patients. There is a trend toward sicker cases with other complicating medical problems, a history of alcohol abuse, noncompliance, and lack of a social support system.[22]

Davis *et al.* described characteristics of "hard-core" TB patients who were not amenable to such compliance strategies as short-course chemotherapy or intermittent chemotherapy. These patients were defined as predominantly male, alcoholic, and having other chronic diseases.[23] A "skid-row" TB patient was described by Caplin and Rehahan as typically male, single and homeless, age 40 to 50, socially isolated, and with a long-standing history of drinking.[24]

Over the most recent two-year period, the hospitalized TB population in Maryland was studied to define more precisely what characterizes these cases, to look at response to treatment, and to give clues to the development of new strategies aimed at minimizing admissions and length of stay while optimizing individual treatment. Since June 1981, Montebello Center has been the only referral hospital in the state of Maryland. Thus, the patients studied were all long-term hospitalizations for this period.

Methods

The survey was conducted as a chart review in January 1984, using an extensive questionnaire that covered information such as basic demographic data (age, sex, race, area of state where the patient resided), reason for admission, length of stay, previous hospitalization, status of smears and cultures, medication, and history of other illness. Given the previously established profile of hospitalized TB patients, details such as reason for admission, history of alcoholism, and compliance behavior were scrutinized.

The study population consisted of all hospitalized TB patients in Maryland admitted between January 1981 and December 1983 to Montebello Center or to Thomas Wilson Center. There were 39 such cases; thirty-seven were admitted to the hospital primarily for tuberculosis. Two cases were admitted for other medical reasons and were found to have tuberculosis during their hospitalization. Two of the 39 had been admitted initially to the Thomas Wilson Center and subsequently were transferred to Montebello Center when Thomas Wilson closed.

After information was gathered on questionnaires, it was coded, entered, verified, edited, and transformed for computer analysis. Using the SPSS® statistical package, cross-tabulations and frequency analyses were performed. More refined statistical analysis of the data was deemed unnecessary because of the small number of cases and the lack of an appropriate comparison group.

Demographics The overall Maryland tuberculosis data from 1979 to 1982 are shown in Table 1.[25] Clearly the trend is toward a decreasing incidence of the disease over time.

For the group under study, the proportion from Baltimore City is 33 percent (Table 1a), similar to that in the overall population of TB patients. As has been found in other studies, the majority of cases were male (77 percent), nonwhite (56.4 percent), and fell into the 40 to 60 year age bracket (54 percent). Nearly 80 percent were alcohol abusers, a figure higher than those cited in other studies (Table 2).[26–28]

In addition, the majority of patients were unmarried, unemployed (including disabled and retired), and had less than ten years' education (64 percent) (Table 3). Twenty-six percent of the hospitalized patients lived alone.

Reason for Admission Of the patients, 56.4 percent were hospitalized for alcoholism with or without noncompliance and with or without severe illness (Table 4). Another 7.7 percent were noncompliant (nonalcoholic, now or in the past). Only four cases (10.3 percent)

Table 1. Recent Trends in TB Cases Reported: Maryland, Baltimore, and the United States: 1979–1982

	1979		1980		1981		1982	
	Number	Rate*	Number	Rate*	Number	Rate*	Number	Rate*
Maryland	648	15.4	610	14.5	621	14.6	540	12.6
Baltimore	293	37.5	274	35.9	275	34.6	221	29.0
USA					27,373	11.9	25,520	11.0

* per 100,000 population

Table 1a. Residential Origin of Tuberculosis Patients Admitted to Montebello Center, 1981–1983

	Number	Percent
Baltimore City	13	33
Maryland Counties	26	67
Total	39	100

Table 2. Demographic Characteristics of TB Patients: Montebello Center and Other Study Series (in percents)

	Montebello	University of Tennessee*	Canadian Center†	Maryland 1980‡
Sex				
Male	76.9	61.7	67.0	62.0
Female	23.1	38.3	33.0	37.0
Race				
White	43.6	51.7		42.0
Nonwhite	56.4	48.3		58.0
Alcohol Abuse	79.5	64.0	28.0	
Age				
Under 50	51.3		37.0	
Over 50	48.7		63.0	
Under 40	23.1			
Over 40	76.9			
Mean Age			51	
Median Age			49	

* Davis, H.L. *et al.* "Characteristics of Hospitalized Tuberculosis Patients Today." *South Med J* 71(1978):1401–5.

† Goldstein, R.S. *et al.* "Tuberculosis—Review of 498 Recent Admissions to Hospital." *Can Med Assoc J* 126(1982):490–92.

‡ State of Maryland Department of Health and Mental Hygiene Statistics.

were admitted purely because of resistant organisms not responding to outpatient treatment. There were other cases of partial resistance but this was not the primary reason for admission. An additional 13 percent were too sick for outpatient care (nonalcoholic). In Dandoy's survey of general and specialized TB hospitals throughout 35 states, the most frequent reason for admission was patients being too sick for outpatient care.[29]

Patient Condition on Admission Sixty-seven percent of the patients were admitted to acute care hospitals before being transferred to Montebello, a finding probably accounting in part for the fact that 15 patients were essentially asymptomatic on admission. Twenty-four patients were symptomatic, including one who was "toxic," due primarily to a combination of tuberculosis and other chronic disease processes.

Laboratory data were remarkable mainly in relation to abnormalities in hematology (56.4 percent with anemia) and liver function (56.4 abnormal either on admission or during hospitalization). There were many possible reasons for these abnormalities.

X-ray examination of the chest was performed at the time of admission and periodically thereafter. Initial readings were largely consistent with the clinical picture of tuberculosis. It was difficult to evaluate progress by the reported x-ray changes. There were inconsistencies between different radiologists and clinicians. The study abstractors did not look at the original films, which might have cleared up some of the difficulty.

Table 3. Other Sociodemographic Characteristics of Montebello Center Patients, 1981–1983

	Number	Percent
Marital Status		
Single	9	23.1
Separated	7	17.9
Divorced	12	30.8
Widowed	5	12.8
Married	6	15.4
Living Arrangements		
Alone	10	25.6
With others	26	66.7
Unknown	3	7.7
Occupation		
Employed	9	23.1
Unemployed	16	41
Disabled	6	15.4
Retired	3	7.7
Unknown	5	12.8
Years of Education		
0–9	25	64.1
10–12	10	25.6
over 12	2	5.1
Unknown	2	5.1

Table 4. Reasons for Admission of TB Patients to Montebello Center, 1981–1983

	Number	Percent
Alcoholism (+/−noncompliance)	22	56.4
Noncompliant	3	7.7
Resistance	4	10.3
Too sick for outpatient care	5	12.8
Mental/physical handicap	3	7.7
Other	2	5.1

Table 5. Montebello Center TB Patients and Associated Chronic Diseases, 1981–1983

	Number
Anemia	22
Malnutrition	8
Diabetes	4
Other G.I.	4
Other Respiratory	3
Cancer	2
Gastrectomy	2
Renal	1

87 percent of the Montebello patients had one or more other chronic diseases.

56.4 percent had a hematologic abnormality.

Other Chronic Diseases It was found that 87 percent of the hospitalized patients had one or more other chronic diseases, with anemia (22 patients) and malnutrition (8 patients) topping the list. Most of these cases were alcoholic. Two patients had had a gastrectomy, and four were diabetic (Table 5). These figures are similar to those in Davis's study with the exception that a hematologic abnormality occurred more fre-

Table 6. Length of Time Between Diagnosis of TB and Admission: Montebello Center, 1981–1983

Number of Months Before Admission	Number	Percent of Patients
0–1	21	53.8
1–2	6	15.4
2–4	3	7.7
4–6	3	7.7
6–12	3	7.7
12–24	1	2.6
24+	2	5.1

Table 7. Number of Previous Hospitalizations for TB: Montebello Center 1981–1983 and Other Study Series

Montebello Center	**Percent**
None	46.2
One	33.3
Two	17.9
Three	2.6
Canadian Center*	20.0 percent had a previous admission
University of Tennessee†	28.9 percent had a previous admission

* Goldstein, R.S. *et al.* "Tuberculosis—Review of 498 Recent Admissions to Hospital." *Can Med Assoc J* 126(1982):490–92.

† Davis, H.L. *et al.* "Characteristics of Hospitalized Tuberculosis Patients Today." *South Med J* 71(1978):1401–5.

quently (56.4 percent versus 8 percent) in the study group.[30]

Length of Time Between Diagnosis and Admission and Length of Stay More than half the patients (53.8 percent) had had their present episode of tuberculosis diagnosed within one month of admission to Montebello Center, and 84.6 percent were diagnosed within six months (Table 6). More than half the patients (53.8 percent) had been previously hospitalized for tuberculosis (Table 7). For such patients it was not always clear whether the present episode of tuberculosis represented a prior treatment failure, reactivation of old tuberculosis, or reinfection.

The mean length of stay at Montebello was 165.3 days, with a median of 147 days. When there was an acute hospitalization for a patient prior to transfer to Montebello, the mean length of stay was 188.6 days with a median of 175 (Table 8). It should be possible to move a very sick patient from an acute care hospital to a lower level of care without loss in the continuity of treatment. Thus it has been suggested that when the days of hospitalization are counted, the number should be cumulative, reflecting care given at both settings.[31]

These data show longer stays at Montebello than those cited in other studies. Dandoy found that the average length of stay ranged from 21 to 163 days in twelve specialized tuberculosis facilities, with half reporting 60 to 90 days.[32] At a tuberculosis sanitorium in Toronto, 80 percent stayed less than six months, and 49 percent less than three months.[33]

Drug Therapy The planned standard course of therapy at Montebello calls for four drugs (usually INH, RIF, streptomycin or ethambutol, and pyrazinamide (PZA)) to be given for two months, followed by two

Table 8. Length of Hospitalization for TB Patients in Days: Montebello Center, 1981–1983, and Other Study Series

	Montebello	Montebello Acute Hospital Stay Combined	General Hospital TBC Admissions*	Canadian Center for TB†	U.S. Survey 1974†	U.S. Survey 1982§
Range	49–467	56–581	1–196		10–101	3–30 (general) 21–163 (specialized)
Mean	165.3	188.6				
Median	147	175			35	
Less than 180 days	56.4 percent			80 percent		

* Dutt, A.K. "Follow-up of Patients with Tuberculosis in a General Hospital Program." *Chest* 74 (1978): 19–23.

† Goldstein, R.S. *et al.* "Tuberculosis—Review of 498 Recent Admissions to Hospital." *Can Med Assoc J* 126 (1982): 490–92.

‡ Dandoy, S. "Current Status of General Hospital Use for Patients with Tuberculosis in the United States: An Update." *Am Rev Respir Dis* 110 (1974): 442–45.

§ Dandoy, S. "Current Status of General Hospital Use for Patients with Tuberculosis in the United States; Eight-year Update." *Am Rev Respir Dis* 126 (1982): 270–73.

Table 9. Combinations of Drug Therapy: Montebello Center Tuberculosis Patients, 1981–83

Patient	Number of Months on Each Drug						
	INH	RIF	ETH	PZA	STREP	ETHIO	CYCLO
1	6*	6*	5*	5*			
2	7*	7*	6*				
3	6*	6*		2*			
4	6*	6*	3				
5	6*	6*	6*				
6	4*	10*	6	4*	1*		
7	8*	8*	3*	2	2		
8		2*		2*			
9	3*	3*	1*	2*	3*		
10		3*	3*			3*	3*
11	7*	7*	4*	2	2		
12	1*	6*	6*	2*	3*		
13	3*	3*	2*	2*			
14	7*	7*		2*	3*		
15	4*	4*	3*				
16		5*	5*	3*	3*		
17	2*	2*					
18	9*	9*	9*		(< 1*)		
19		9*	7				
20	12*	12*	8*				
21	2*	2*		(< 1)	2*		
22	4*	4*		3*	3*		
23		5*	2	4*		1	(< 1)
24	2*	8*	8*				
25	9*	9*	2*	2*	3*		
26			4*	4*		4*	4*
27				5*		5	5
28		8*	8*	3	4*		3
29	6*	6*				1	1
30	9*	9*	9*				
31		3*	3*	3*	3*	3*	
32	2*	2*	2*				
33	7*	7*	3*	3*			
34		4*	4*				
35	8*	8*	7*				
36	2*	6	6	2*	1*		
37		2*		2*	2*		
38	3*	3*					
39		2*	2*	2*			

Number of Drugs	Number of Patients
2	4
3	16
4	10
5	9
≥ 2 month INH	26
≥ 2 month RIF	36
≥ 2 month INH + RIF	26

Planned regimen of INH+RIF+ETH (or strep)+PZA – 13 patients
Part of regimen, INH+RIF+ETH – 20 patients

* Initial drug therapy on admission to Montebello

drugs (usually INH and RIF) for another seven months. The drug treatment for each patient and the length of time on each drug are presented in Table 9. In this group of patients, for the entire hospitalization, 8 received five drugs, 11 received four drugs, 15 received three drugs, and 5 patients received two drugs. RIF was the most frequently used drug, with 37 patients receiving it for at least two months. INH was used in 26 patients for a minimum of two months. Twenty-six patients received both INH and RIF for two or more months. One patient who was severely noncompliant and had drug resistant tuberculosis underwent a right upper lobectomy.

Drug resistance was a minor problem. A total of eight patients had some degree of drug resistance on admission, but only four of these cases were hospitalized for this reason. Four others had some degree of INH resistance that did not pose a major problem. After admission, two other patients were discovered to have INH resistance and one had streptomycin resistance.

Major drug side effects were unusual. Twenty-six patients (66.7 percent) were not observed to have any prominent side effects (Table 10, next page). Seven patients developed gastrointestinal symptoms (one patient being admitted with a resolving INH hepatitis), three had dermatologic problems, and three had miscellaneous reactions for a total of 12 patients. Five patients developed uric acid elevations (a side effect of PZA), but there was no case of clinical gout. No visual or auditory toxicity were detected. For only a few pa-

Table 10. Side Effects of Anti-Tuberculous Chemotherapy: Montebello Center Patients, 1981–83

	Number of Patients
None	26
Gastrointestinal	7
Skin	3
Other	3
Elevated uric acid	5

Table 11. Status of Smears/Cultures on Admission: Montebello Center TB Patients, 1981–1983

Admission status of smear/culture	Number	Percent
Either positive smear or culture	19	48.7
Positive smear and positive culture	15	38.5
Negative smear and positive culture	3	7.7
Positive smear and negative culture	1	2.6
Negative smear and negative culture	20	51.3

Of those with positive smear and/or culture on admission, length of time to convert:

Time (in weeks)	Number	Percent
0–2	2	10.5
2–4	2	10.5
4–6	2	10.5
6–8	4	21.1
8+	6	31.6
Did not convert	3	15.8
Total	19	

Table 12. Manifestations of Tuberculous Infection: Montebello Center Patients, 1981–1983

	Number	Percent
Pulmonary (M. tuberculosis)	31	82
Pulmonary (Intracellulare)	3	7.7
(Kansaii)	1	2.6
Pleural Effusion	1	2.6
Meningitis	1	2.6
Hematogenous	1	2.6
Bone	1	2.6

tients a drug or drugs had to be stopped because of side effects. In those cases, it was difficult to separate side effects from underlying disease processes.

Status of Smears and Cultures At the time of admission, 19 patients (48.7 percent) had a positive smear and/or culture; 17 of these patients were alcoholic. Of the 20 patients with negative smears and cultures on admission, many had been started on chemotherapy in the acute referring hospital or outpatient clinic.

Of those patients with a positive smear or culture on admission who ultimately converted (16 patients), 52.5 percent converted to negative smear and culture within two months (Table 11). By three months, 87.5 percent converted, and all converters did so by six months (longest was 22.4 weeks).

Of the three patients who left the hospital without converting, one patient with Mycobacterium intracellulare left against medical advice with a positive smear, one left with a positive culture, and one was discharged with a positive smear and culture, having Mycobacterium intracellulare.

Types of Tuberculosis As expected, the majority of cases were of M. tuberculosis pulmonary disease (Table 12). Three patients had M. intracellulare, and one patient had M. kansasii. Exclusively extrapulmonary tuberculosis was seen in 7.8 percent (three patients), a figure lower than that cited in the 1980 statistics for Maryland (17 percent) and Baltimore City (16 percent).[34]

Status at Discharge Information about patients at the time of the discharge is presented in Table 13: 74.4 percent were regarded as improved, and 12.8 percent were considered unchanged; 84.6 percent completed the full hospital course of treatment. Five patients left

Table 13. Discharge Information: Montebello Center TB Patients, 1981–1983

	Number	Percent
Patient status at discharge		
Same	5	12.8
Improved	29	74.4
Condition Worsened	3	7.7
Unknown	2	5.1
Type of facility to which patient referred		
Hospital	1	2.6
Long-term care	4	10.3
City or county Health Department	25	64.1
Other	9	23.0
Reason for discharge		
Treatment completed	33	84.6
PT. Left A.M.A.	5	12.8
Other	1	2.6

against medical advice, and one of these had to be incarcerated to continue his course of treatment. Most patients were discharged to be followed up as outpatients. There were no deaths in this group.

Discussion

The study population represents TB patients most recently hospitalized in a long-term care setting in Maryland. To a large extent, it fits the usual patient profile described in the literature.[35,36] Many workers involved with tuberculosis programs find the single, unemployed, male alcoholic is most likely to be noncompliant.[37] The hospitalized patients were predominantly male, middle-aged, nonwhite, and alcoholic. They demonstrated a very high degree of alcoholism, more so, in fact, than seen in other studies, with this disease being the primary cause of admission in over three quarters of the patients. Noncompliance, chronic illness (malnutrition and anemia), and overall illness severe enough to obviate outpatient care were usually secondary to the alcoholism. Significant tubercle bacillus chemotherapy resistance was unusual.

An adverse social situation such as living alone, chronic unemployment, or lack of education was not regarded as a primary cause for hospitalization in any patient. However, three patients who were mentally or physically handicapped were admitted. When a difficult social situation was present, it was usually secondary to alcoholism.

Each recent year has seen a substantial drop in the rate of tuberculosis in Maryland. As the incidence decreases, the profile of the hospitalized TB patient can be expected to reflect a sicker, more complicated, and more socially displaced patient.

The long length of hospital stay seems to reflect this distillation process, with the final "residue" being a very ill, uncooperative, alcoholic patient requiring prolonged care and supervision, as much for the complicating factors of alcoholism as for the tuberculous process.

After examining the characteristics of the study population at Montebello, we concluded that the noncompliant alcoholic is the most difficult TB patient to treat. This group needs to be dealt with, and the challenge is to develop methods to do so in a cost-effective manner. At Montebello, the plan has been to initiate and administer chemotherapy in the hospital setting for six months; thus a fairly lengthy hospitalization occurs by design.

While in the hospital, patients undergo social and psychiatric evaluation, become involved in group therapy, Alcoholics Anonymous, and physical therapy when indicated. Consultations from other services such as Orthopedics and Dental are provided. This multipronged approach has been the backbone of an effort at total rehabilitation. In such a structured environment, more patients are likely to complete therapy. Most patients, in fact, did respond to such an approach, and the majority improved and smear/culture was negative at discharge. There were a few recalcitrant patients who, despite all efforts, signed out against medical advice; one patient eventually was incarcerated in order to complete treatment.

The ultimate hope is to be able to diagnose and treat tuberculosis while outpatient care is still feasible. It is of overriding importance to diagnose and treat chronic alcoholism. The American Medical Society on Alcoholism strongly recommends treatment of alcoholism to begin simultaneously with tuberculosis treatment.[38]

McDonald *et al.* have described a successful regimen of ambulatory treatment of recalcitrant patients, most of whom were alcoholics. The authors emphasize social and compliance strategies as well as drug therapy.[39] Others have suggested aggressive screening of alcoholics at reception centers, soup kitchens, and the like, to pick up cases early in this vulnerable group.[40] They also have proposed establishing hostels for homeless alcoholic TB patients while under treatment.[41]

It never will be possible to eliminate totally the need for long-term institutional care for some TB patients. However in 1984, specialized units were unnecessary if some other setting was available, either a long-term care institution such as a nursing home, a halfway house setting, or supervised ambulatory chemotherapy. The most appropriate setting will depend on the patient's overall needs and not exclusively on the diagnosis of tuberculosis. Reducing the number of hospitalized TB patients will depend on devising ways to encourage compliance, especially in alcoholics. Since a large number of these patients are unemployed and receiving federal and/or state support, financial assistance could be made contingent on compliance with ambulatory therapy.

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Osteoarthritis, VI: The Hip—Surgical Management

DENNIS W. LENNOX MD

Dr. Lennox is Assistant Professor, Department of Orthopaedic Surgery, The Johns Hopkins University, School of Medicine, Baltimore, MD.

A number of assumptions underlie this discussion of the surgical treatment of osteoarthritis of the hip. First, it is assumed that osteoarthritis as a diagnosis has been firmly established. Thus such underlying disorders as septic arthritis, rheumatoid arthritis, seronegative spondyloarthropathies, pigmented villonodular synovitis, synovial chondromatosis, and neoplasm have been excluded. Particularly with younger patients, a previous history of avascular necrosis, Legg-Perthes' disease, congenital hip dysplasia, or slipped capital epiphysis may produce a roentgenographic picture similar to if not indistinguishable from osteoarthritis. So-called "secondary" osteoarthritis associated with hemochromatosis, Wilson's disease, ochronosis, Gaucher's disease, hemoglobinopathies, Ehlers-Danlos Syndrome, endocrine disorders, bone dysplasias, calcium crystal deposition disease, neuropathic arthropathy, Paget's disease, osteopetrosis, and other rare disorders may confuse the diagnostic process.

Another assumption is that attempts at nonsurgical therapy have failed to provide adequate pain relief or mobility. Such nonsurgical modalities might include exercises, anti-inflammatory agents, soft tissue or intra-articular injections, heat, cold, ultrasound, transcutaneous electrical nerve stimulation, traction, massage, adaptive aids, and environmental design and education. The use of orthotic devices does not apply to hip disorders. However, the use of a cane, crutches, or walker can be beneficial in many cases and may delay or avoid surgery. If, having established the diagnosis of osteoarthritis of the hip and having attempted nonsurgical modalities of therapy, significant pain and disability persist, then operative intervention can be considered.

General indications for operative treatment are pain, deformity, and limitation of function. A number of factors interact to determine optimal management of osteoarthritis of the hip. These include patient factors such as weight, age, activity level, disability, pain level, and overall medical condition. A factor that may be of major importance and yet has received little attention is patient attitude and expectations regarding surgery. Other considerations include the extent and severity of involvement of the hip, the state of the art of treatments available, and the technical ability, experience, and judgment of the operating surgeon.

Timing of surgery can be important. Although osteoarthritis of the hip is not life threatening, it can be rapidly progressive and disabling. Waiting beyond a certain point in the disease progression may compromise the final surgical result. Factors such as marked bony erosion, severe soft tissue contractures or muscular weakness, severely restricted motion, or osteopenia may preclude a lesser procedure or adversely affect the final result of a major operation.

Preoperative medical management should be optimal. Of particular importance prior to surgery is the treatment of emergent conditions such as GI blood loss, anemia, urinary or pulmonary infections, myocardial incompetence, diabetes, and COPD. Many believe that those patients for whom a metallic implant is planned should undergo a dental exam and treatment as needed prior to hip surgery to avoid the risk of bacterial seeding of the implant at a later date as a result of dental work. Medical conditions that appear to add to the morbidity of major hip surgery include bladder-neck obstruction, a history of previous thrombophlebitis, and preoperative abnormal renal function.[1-3]

Many patients with osteoarthritis are good candidates for an autologous blood transfusion program. With the use of this technique, the risk of introducing transfusion hepatitis or a transfusion reaction is minimized.

Several types of surgical procedures are currently available for treating osteoarthritis of the hip. These include osteotomy, arthrodesis, and arthroplasty.

Osteotomy

Osteotomy addresses the mechanical factors involved in the pathophysiology of osteoarthritis in that it realigns the hip joint to redistribute hip joint stresses across healthy cartilaginous surfaces.

The cartilage surfaces of the acetabulum and femoral head are left intact. Only the alignment is altered by osteotomy. One form of osteotomy includes the removal of a wedge of bone from the femur at the region between the greater and lesser trochanters (intertrochanteric osteotomy). Having removed this wedge, the surfaces thus created are opposed and fixed with a plate and screws. This realigns the hip joint (Figure 1, next page).

In addition, there appears to be the advantage of a biologic effect of osteotomy in that simply cutting the bone tends to normalize the vascular pattern and may relieve pain.[4] The typical patient who might benefit from an osteotomy of the hip is a young (less than 50 years old), active individual with functional hip range of motion, incompletely destroyed cartilage surfaces, good muscular control of the hip and focal changes of osteoarthritis in the femoral head alone or in combination with focal changes in the acetabulum. If by routine roentgenograms, tomograms, or CT scan it appears that the weight-bearing surfaces of the hip joint can be broadened (thus diminishing the unit contact stress) by osteotomy, then either a femoral or supra-



Figure 1. An osteotomy of the hip has been performed to redistribute the weight-bearing forces across this hip. The osteotomy has been fixed with a blade plate and screws.

acetabular (pelvic) osteotomy (or both) may be indicated. Although such a procedure is not expected to be curative, it can provide significant symptomatic relief with good long-term results.

Arthrodesis

The primary indication for considering arthrodesis (fusion) of the hip exists in the young, short, active male with a unilateral painful destroyed hip, especially when destroyed by septic arthritis. Arthrodesis can provide a pain-free stable hip for many years. At a later time, the arthrodesis often can be converted to a total hip arthroplasty. Hip fusion does present excessive forces to the lumbar spine, ipsilateral knee, and contralateral hip. Thus, joint disease in these locations may represent a relative contraindication to the procedure. The limitation of mobility of the hip imposed by arthrodesis can present a serious problem, especially in tall individuals. Arthrodesis of the hip often requires prolonged partial weight-bearing ambulation and cast immobilization for a number of months. Although arthrodesis of the hip is only rarely performed in the United States, in the appropriately selected individual this procedure can provide a stable, pain-free hip that can withstand vigorous and strenuous activities. Arthrodesis may be particularly attractive in cases of deficient bone stock or inadequate muscular control of the limb.

Arthroplasty

A number of operative options exist within this major category of hip arthritis surgery. Two ends of the spectrum within this category are represented by mold arthroplasty and total hip arthroplasty. In mold arthroplasty a metallic cup is interposed between the femoral head and acetabulum, after these surfaces have been denuded of arthritic involvement. In total hip arthroplasty a prosthetic device is inserted into the acetabulum and into the femoral shaft thus replacing both the head and neck of the femur as well as the acetabular cup. Intermediate procedures exist between these two extremes. One is resurfacing in which arthritic changes on the femoral head are removed and the region replaced by a metallic cup, while on the acetabular side a polyethylene acetabular component is inserted. Another option is femoral hemiarthroplasty (endoprosthesis) in which the femoral head and neck are resected and a metallic device is inserted into the femoral canal to replace the arthritic femoral head. With the use of hemiarthroplasty only one side of the joint is altered; the acetabular side remains intact.

Mold Arthroplasty (Cup Arthroplasty)

Smith-Peterson reported good results with the use of mold arthroplasty in osteoarthritis of the hip. This procedure consists of interposing a metallic cup between the femoral head and acetabulum. Prior to insertion of the cup, the surfaces of the femoral head and acetabulum are reamed to bleeding bone. With time and motion, fibrocartilage and occasionally hyaline cartilage are formed.[5]

Although the results with this technique were good and occasionally outstanding, the degree of pain relief was generally much less than that achieved with total hip arthroplasty, and for that reason, mold arthroplasty is only infrequently performed today.

Femoral Hemiarthroplasty

In femoral hemiarthroplasty, the arthritic femoral head as well as most of the femoral neck is resected and a metallic device is inserted into the femoral canal (Figure 2, next page). When acetabular cartilage is normal or only minimally involved by osteoarthritis, hemiarthroplasty (femoral endoprosthesis) thus offers the advantage of preservation of "normal" acetabular cartilage. However, if in time erosion of acetabular cartilage does occur, conversion to a total hip arthroplasty may be required.

Resurfacing

Hip resurfacing usually involves insertion of a prosthetic acetabular component as well as replacement of the surface of the femoral head with a metallic cup. Thus, the femoral neck is preserved with this procedure (Figure 3). Hopes for this procedure were high, since it preserved the bone stock for subsequent revision surgery, should it become necessary. Although the initial results from numerous centers were promising, long-term results have indicated a progressive incidence of femoral neck fracture and loosening. In the hands of physicians who are experienced in this technique and strongly believe in the concept of resurfacing, the results with this procedure appear to be good, most surgeons prefer total hip arthroplasty rather than the resurfacing procedure.

Total Hip Arthroplasty

Low friction arthroplasty of the hip (total hip replacement) as pioneered and popularized by Charnley, generally provides excellent pain relief, range of motion, and function. The predictability of good-to-excellent results obtained with this procedure have made total hip arthroplasty exceedingly popular today, particularly for the elderly patient with osteoarthritis of the hip.

Although the short-term results with total hip arthroplasty are excellent, application of this surgical procedure to younger age groups has led to an increasing incidence of aseptic loosening, the major complication of the surgery. Although one series reported a 1.5 percent loosening rate in 409 Charnley low friction arthroplasties reviewed 11.5 years after surgery, another review of total hip arthroplasties at 5 years following surgery reported a 57 percent revision rate. The significant difference between the two reports is the average age of the patient population, 68 years for the Charnley group and less than 30 years for the higher revision rate group.[6,7] With the present state of the technology, total hip replacement cannot be guaranteed to last a lifetime in the younger, more active patient.

Traditionally, polymethylmethacrylate cement has been used to fix prosthetic implants to bone. The interface thus formed between the plastic cement and the bone represents the weakest link in the system of total hip arthroplasty. It is at this interface that loosening of hip prostheses occurs.[8] Alternative techniques of fixation and advances in implant design may decrease the problem of loosening in the future. Many centers are now investigating different means of fixing the implants to bone, avoiding the use of bone cement. One of the major areas of investigation has been the use of porous-surface implants to allow bone ingrowth and



Figure 2. Hemiarthroplasty of the hip involves replacement of the head and neck of the femur. In this case the intramedullary stem was cemented to the femur. The acetabulum remains intact with this surgery.



Figure 3. Hip resurfacing preserves the neck of the femur and replaces the acetabulum and involved surface of femoral head.

provide for biologic fixation (Figure 4). Another approach to implant fixation has been the use of a ceramic articular surface with an extremely low coefficient of friction. Although the results from both of these new fixation methods appear to be excellent in the short term, long-term evaluations of prosthetic loosening and failure are required before conclusions can be drawn regarding the efficacy of cementless fixation.

Girdlestone Arthroplasty of the Hip

In 1943, Girdlestone described an operative procedure for pyogenic arthritis of the hip in which the head and neck of the femur were excised and a fibrous pseudarthrosis developed. This represents a type of excisional arthroplasty of the hip and is a salvage procedure most often performed after failure of total hip arthroplasty or other hip surgery. Excellent results are seen only rarely with excisional arthroplasty, and external supports (cane or crutches) are usually required for most activities.

Summary

A number of surgical options exist for the treatment of osteoarthritis of the hip. Optimal management of patients with osteoarthritis of the hip includes an individualized approach to each patient, considering patient factors such as age, weight, level of activity, medical condition, pain, disability, and attitude regarding surgery. Of all the operative procedures available to treat severe osteoarthritis of the hip, the most reliable and reproducibly good-to-excellent results are obtained with total hip arthroplasty. However, there is a high incidence of aseptic loosening associated with this procedure in young individuals. Total hip arthroplasty represents a rapidly evolving technology, and future developments in biomaterials and fixation methods may produce a prosthesis better suited to young, more active patients.



Figure 4. On the right (R) an uncemented total hip arthroplasty has been performed. Note the absence of radio-opaque cement around the femoral stem and acetabular component. On the left is a cemented total hip arthroplasty. Wire markers in the cemented acetabular component are used to determine orientation of the prosthetic cup.

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WARNINGS: The benefits of SORBITRATE during the early days of an acute myocardial infarction have not been established. If one elects to use organic nitrates in early infarction, hemodynamic monitoring and frequent clinical assessment should be used because of the potential deleterious effects of hypotension.

PRECAUTIONS: General: Severe hypotensive response, particularly with upright posture, may occur with even small doses of SORBITRATE. The drug should therefore be used with caution in subjects who may have blood volume depletion from diuretic therapy or in subjects who have low systolic blood pressure (eg, below 90 mmHg). Paradoxical bradycardia and increased angina pectoris may accompany nitrate-induced hypotension. Nitrate therapy may aggravate the angina caused by hypertrophic cardiomyopathy.

Marked symptomatic, orthostatic hypotension has been reported when calcium channel blockers and organic nitrates were used in combination. Dose adjustment of either class of agents may be necessary.

Tolerance to this drug and cross-tolerance to other nitrates and nitrites may occur. Tolerance to the vascular and antianginal effects of isosorbide dinitrate or nitroglycerin has been demonstrated in clinical trials, experience through occupational exposure, and in isolated tissue experiments in the laboratory. The importance of tolerance to the appropriate use of isosorbide dinitrate in the management of patients with angina pectoris has not been determined. However, one clinical trial using treadmill exercise tolerance (as an end point) found an 8-hour duration of action of oral isosorbide dinitrate following the first dose (after a 2-week placebo washout) and only a 2-hour duration of effect of the same dose after 1 week of repetitive dosing at conventional dosing intervals. On the other hand, several trials have been able to differentiate isosorbide dinitrate from placebo after 4 weeks of therapy and, in open trials, an effect seems detectable for as long as several months.

Tolerance clearly occurs in industrial workers continuously exposed to nitroglycerin. Moreover, physical dependence also occurs since chest pain, acute myocardial infarction, and even sudden death have occurred during temporary withdrawal of nitroglycerin from the workers. In clinical trials in angina patients, there are reports of anginal attacks being more easily provoked and of rebound in the hemodynamic effects soon after nitrate withdrawal. The relative importance of these observations to the routine, clinical use of isosorbide dinitrate is not known. However, it seems prudent to gradually withdraw patients from isosorbide dinitrate when the therapy is being terminated, rather than stopping the drug abruptly.

Information for Patients: Headache may occur during initial therapy with SORBITRATE. Headache is usually relieved by the use of standard headache remedies or by lowering the dose and tends to disappear after the first week or two of use.

Drug Interactions: Alcohol may enhance any marked sensitivity to the hypotensive effect of nitrates.

Isosorbide dinitrate acts directly on vascular smooth muscle, therefore, any other agent that depends on vascular smooth muscle as the final common path can be expected to have decreased or increased effect depending on the agent.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term studies in animals have been performed to evaluate the carcinogenic potential of this drug. A modified two-litter reproduction study in rats fed isosorbide dinitrate at 25 or 100 mg/kg/day did not reveal any effects on fertility or gestation or any remarkable gross pathology in any parent or offspring fed isosorbide dinitrate as compared with rats fed a basal-controlled diet.

Pregnancy Category C: Isosorbide dinitrate has been shown to cause a dose-related increase in embryotoxicity (increase in mummified pups) in rabbits at oral doses 35 and 150 times the maximum recommended human daily dose. There are no adequate and well-controlled studies in pregnant women. SORBITRATE should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when SORBITRATE is administered to a nursing woman.

Pediatric Use: The safety and effectiveness of SORBITRATE in children has not been established.

ADVERSE REACTIONS: Adverse reactions, particularly headache and hypotension, are dose-related. In clinical trials at various doses, the following have been observed.

Headache is the most common (reported incidence varies widely, apparently being dose related, with an average occurrence of about 25%) adverse reaction and may be severe and persistent. Cutaneous vasodilation with flushing may occur. Transient episodes of dizziness and weakness, as well as other signs of cerebral ischemia associated with postural hypotension, may occasionally develop (the incidence of reported symptomatic hypotension ranges from 2% to 36%). An occasional individual will exhibit marked sensitivity to the hypotensive effects of nitrates and severe responses (nausea, vomiting, weakness, restlessness, pallor, perspiration, and collapse) may occur even with the usual therapeutic dose. Drug rash and/or exfoliative dermatitis may occasionally occur. Nausea and vomiting appear to be uncommon. Case reports of clinically significant methemoglobinemia are rare at conventional doses of organic nitrates. The formation of methemoglobin is dose-related and, in the case of genetic abnormalities of hemoglobin that favor methemoglobin formation, even conventional doses of organic nitrate could produce harmful concentrations of methemoglobin.

DOSAGE AND ADMINISTRATION: For the treatment of angina pectoris, the usual starting dose for sublingual SORBITRATE is 2.5 to 5 mg; for chewable tablets, 5 mg; for oral (swallowed) tablets, 5 to 20 mg; and for controlled-release forms, 40 mg.

SORBITRATE should be titrated upward until angina is relieved or side effects limit the dose. In ambulatory patients, the magnitude of the incremental dose increase should be guided by measurements of standing blood pressure.

The initial dosage of sublingual or chewable SORBITRATE for prophylactic therapy in angina pectoris patients is generally 5 or 10 mg every 2 to 3 hours. Adequate controlled clinical studies demonstrating the effectiveness of chronic maintenance therapy with these dosage forms have not been reported.

SORBITRATE in oral doses of 10 to 40 mg given every 6 hours or in oral controlled-release doses of 40 to 80 mg given every 8 to 12 hours is generally recommended. The extent to which development of tolerance should modify the dosage program has not been defined. *The oral controlled-release forms of isosorbide dinitrate should not be chewed.*

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Medical Miscellany

A Medication Record for Asthmatics

During the 1978–79 school year, a survey was done to determine the extent of utilization of health services by asthmatic elementary school children in Baltimore City and surrounding counties. Conducted by the Departments of Pediatrics, Epidemiology and Biostatistics, Johns Hopkins Medical Institute, and the American Lung Association of Maryland, it was supported by the Hospital for Consumptives of Maryland (Eudowood). Among the findings was that almost half the children with asthma in Baltimore City obtained their treatment in the emergency room, indicating that a large proportion of these children were receiving episodic treatment rather than continuing care for this condition.

One of the objectives of the Pediatric Lung Disease Committee of the American Lung Association of Maryland is to assist with the delivery of community resources and health services presently available. In an effort to provide the asthmatic with continuity of care, a "Medication Record for Asthmatics" was developed with the help of the University of Maryland Hospital's Asthma Committee.

It is our hope that this handy, wallet-size card will assist the health care provider in treating the asthmatic in the event of an emergency. The card contains the name and address of the patient, an emergency contact, name and telephone number of the patient's physicians, allergies to drugs, and available space to list all the patient's medications.

For the card to be useful and effective, the following guidelines are recommended to the health care provider:

1. Emphasize to the patient the importance of carrying the medication record at all times.
2. Ask the patient for the medication record at each visit (even if there is no change in medication).
3. Inform the patient that information related to prescribed medications, (dose, date started and stopped, and frequency of use) should be recorded only by a health care provider.
4. Cross out any discontinued medication.
5. Issue a new medication record when there is no available space on the old card to list additional medications.
6. Medication records should indicate only long-term drug use; it is not necessary to record those medications prescribed to battle acute episodes.

It is hoped that every patient who carries the card will help himself/herself and the medical profession by alleviating any confusion concerning current medications.

The American Lung Association of Maryland will provide copies of the "Medication Record for Asthmatics" upon request. Call 685-6484 or toll free 1-800-492-7527 (in Maryland only).

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Safety Agency Seeks Help of Medical Professionals in Gathering Injury Data

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The Consumer Product Safety Commission gathers data from a variety of sources, but a number of serious injuries and fatalities still go unreported. CPSC would like to expand its coverage. CPSC believes that individuals and organizations in the medical profession are in an excellent position to detect injuries caused by consumer products that may be unacceptably hazardous, and the agency invites reports where a consumer product may have played a significant role in an accident.

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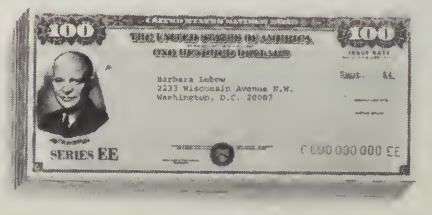


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PAUL G. MUELLER MD

Dr. Mueller is Chairman, Department of Emergency Medicine, Mercy Hospital, Batimore; and Associate in Medicine, University of Maryland Medical School, Baltimore, MD.

Toxic reactions from radiographic contrast material or other agents may be severe and life threatening, requiring rapid treatment to prevent serious complications or death. Although radiologists are most often confronted by such reactions, familiarity by other health care providers is essential. Radiographic tests usually are ordered by internists, neurologists, emergency physicians, and urologists, and occasionally it may be necessary for them to treat or prevent serious reactions. Also reactions may be caused by agents other than radiographic contrast material and may be seen first in the Emergency Department.

The two following cases seen in our Emergency Department required intensive treatment. One could have ended in death without proper immediate attention.

Case Reports

Case 1 A 42-year-old white female received radiographic contrast material for a CAT study of her brain. The CAT study was ordered to assist in the determination of the etiology of headache. The history revealed chronic headache with increasing severity of symptoms over several months. Shortly after administration of the contrast material, the patient complained of body warmth, flushing, substernal chest pain, and abdominal pain with cramping and nausea, followed by vomiting and shaking chills. Physical examination revealed a well-defined erythematous, macular skin eruption located on her torso and face. The lesions were 1 to 2 cm in diameter. Her blood pressure was 110/70, and her pulse was 90. The rest of the physical examination was negative except for obesity and evidence of anxiety and apprehension.

Following administration of epinephrine (0.3 cc in a 1 to 1000 solution in water, subcutaneously), the patient's ECG showed nonspecific ST segment changes that were compatible with, but not diagnostic of ischemia.

Another subcutaneous injection of epinephrine was followed by benadryl, 50 mg intramuscularly. An intravenous infusion of 5 percent dextrose in water was started at 200 cc per hour. Oxygen was administered at 3 liters per minute by nasal canula. One hundred mg hydrocortisone was given intravenously. Forty-five minutes after the administration of epinephrine, benadryl, oxygen and intravenous fluids, the chills were no longer present, the nail beds were still slightly cyanotic, and only a few macules remained on the posterior chest. One hour and forty-five minutes after the beginning of the treatment the patient was asymptomatic except for a few remaining macules on her back. She was admitted to the hospital, and on the next day she was discharged.

Case 2 A 56-year-old white male was receiving radiographic contrast material in a radiologist's office in preparation for intravenous pyelography when he developed generalized urticaria and hypotension. He was given 50 mg of benadryl intramuscularly. Minutes later he showed no improvement, and was taken to the Emergency Department. On admission to the Emergency Department he had deep cyanosis of the lips and fingernail beds with dark blue mottling of the skin. His pulse was 92, and his blood pressure was 90/60. The patient was tachypneic and heart sounds were too distant to evaluate. Radial pulses were not palpable. The abdominal examination was normal.

Arterial blood gases on room air were Ph 7.41, $PO^2$92, PCO^2 33, O^2 saturation 97 percent. An EKG revealed ST segment changes compatible with ischemia. Treatment was started immediately with 0.3 cc of 1 to 1000 epinephrine in water subcutaneously. An intravenous drip of 5 percent dextrose in water was started, wide open. After 30 minutes intravenous normal saline (150 cc per hour) was started. Five hundred mg of hydrocortisone was given intravenously and a dopamine drip was started. Because of the extremely poor perfusion, an additional injection of epinephrine (0.3 cc of 1 to 1000 in water) was given intravenously very slowly. The blood pressure remained between 70/50 and 105/70 while in the Emergency Department.

Approximately three and one-half hours after arriving in the Emergency Department, the patient was admitted to the Intensive Care Unit. In the Intensive Care Unit, the patient was maintained on intravenous fluids and dopamine. He developed frequent premature ventricular beats and several short runs of ventricular tachycardia, thought to be due to the dopamine. The ventricular dysrhythmia was treated successfully with lidocaine. The blood pressure remained normal throughout the patient's hospital stay. He was discharged in good condition on the third day.

Discussion

Anaphylactoid reactions to contrast materials are uncommon, occurring in 1.7 percent of patients receiving the material with a death rate of 1 in 50,000 pyelogram procedures.[1] With the increase in the use of such materials for multiple radiologic procedures, an increase in the incidence of such reactions might be expected. These reactions occur without prior exposure to the material. Subsequent challenge to the material may be without incident. Only about 1 in 5 patients will react the second time.[2]

Common mild reactions or "side effects" from radio-

graphic contrast material include pain in the arm, flushing, metallic taste in mouth, faintness, paresthesias, nausea, vomiting, and cough. True anaphylactoid reaction consists of any of the above symptoms plus pruritis, urticaria, stridor, wheezing, dyspnea, cyanosis, hypotension, coma, dysrhythmias, and death.

This clinical picture is caused by the direct action of the substance on cells (that is, mast cells and basophils), with degranulation of the cell, releasing histamine that causes dilatation of the capillaries and venules with subsequent surrounding flare and edema, secondary to increased vascular permeability.[3] This reaction takes place not only in the skin but also in the lining of the respiratory tract with edema of the upper and lower respiratory tract. Subsequently stridor, bronchospasm, hypoxia, asphyxia, respiratory acidosis, cardiac dysrhythmias, and death may occur. Certain mediators and chemotactic factors also are released that, by their activity, increase tissue inflammation and swelling. Release of these factors is caused by materials such as radiographic contrast material, curarilike agents, opiates, polymyxins, dextran, amphetamines, shellfish, aspirin, azodyes, thiamine, hydralazine, alcohol, and atropine.

Some believe the severity of the reaction may be directly or proportionately related to the strength of the solutions and/or the rapidity with which it is given. In this institution the contrast media is infused rapidly prior to performing the procedures.

Post mortem examinations usually reveal acute pulmonary emphysema, laryngeal edema, and visceral congestion. In some cases, there are no pathological findings.

Treatment

Discussion will be limited to severe or anaphylactoid reactions because mild reactions require no specific therapy other than discontinuing the drug.

1. Discontinue the injection of radiographic contrast material.

2. Epinephrine, 1 to 1000 in water, 0.3 to 0.5 ccs is administered subcutaneously immediately. It is important to remember that when the patient is in peripheral vascular collapse, poor perfusion is a problem. Therefore, the epinephrine may be given intravenously very slowly, using epinephrine 1 to 10,000 and in doses from 1 to 5 ccs. Epinephrine also may be given in intravenous drip using a concentration of 4 μg/ml (1 ml of 1:1000 dilution of epinephrine, added to 250 cc of 5 percent dextrose in water). The drip should be titrated according to response, starting at 1 μg/minute and increasing to 4 μg/minute, if necessary.[4]

The dilution of epinephrine 1 to 1000 in water administered intravenously as done in Case No. 2 may be hazardous.[5]

Dilutions of 1:100,000 as recommended by Baroch *et al.*[6] for intravenous use probably should be reserved for patients with a strong history of cardiovascular disease. In the opinion of this author, the 1:10,000 dilution is more appropriate in catastrophic anaphylactoid reactions. It is important to remember that this medication also may be given directly into an endotracheal tube; 10 cc of 1:10,000 solution (1 mgm) is instilled through a catheter.[7] The catheter tip should reach the end of the endotracheal tube. The patient should be hyperventilated for a short time after installation of the epinephrine. The interval between doses should be lengthened when endotracheal administration is used since blood levels remain elevated longer with this route of administration. Epinephrine is the cornerstone of therapy and not to be neglected or left to last, as in Case No. 2.

3. Intravenous fluid therapy should be started early, via a large bore canulae. Normal saline solution or Ringers-lactate is preferred; large amounts may be necessary to correct the hypovolemia. The volume administered should be determined by the patient's response or the values obtained with hemodynamic monitoring.

4. Diphenhydramine, 50 mgm is administered intramuscularly or intravenously.

5. If the basic treatment of epinephrine and diphenhydramine is unsuccessful, electrocardiographic and hemodynamic monitoring are necessary to guide more intensive therapy.

6. Hydrocortisone is given intravenously in doses from 200 to 500 mg. Other steroid medications may be substituted in doses equivalent to the above.

7. Aminophylline. When bronchospasm is a problem and persists despite use of epinephrine, aminophylline should be administered, 5 mgm/Kgm of body weight, intravenously in 20 minutes followed by an intravenous drip of 0.6 mgm/Kgm of body weight per hour.

8. Oxygen, by nasal canula, 4 to 6 liters per minute is started.

9. Should access to veins not be rapidly available, endotracheal intubation should be done. Epinephrine, as well as other drugs, may be administered via the tube.

10. Dopamine: This drug may be used in hemodynamically significant hypotension that is unresponsive to epinephrine or appropriate fluid administration. It should be administered at a rate of 2–5 μg/Kg/minute, initially. Dosage should then be adjusted according to response but not to exceed 40 μg/Kg/minute, except for extreme cases.

An easy way to administer Dopamine is to multiply the patient's weight in Kg by 15, to obtain the amount

of drug in mg that is added to 250 ml of 5 percent dextrose in water. When this mixture is administered through a microdrip pump, a dial setting of 15 will give 15/μg/KG/minute, etc.[8]

Nausea, hypotension, bradycardia and syncope may occur due to excessive vagal stimulation (vasovagal reaction). Elevation of the lower extremities and/or the administration of atropine will correct the problem.

Prevention

Because they are potentially hazardous, radiological procedures requiring the use of contrast media should be done only when definitely indicated. Skin tests are not helpful in identifying patients susceptible to this reaction.

Patients who have had reactions and for whom the procedure is strongly indicated may be given prednisone, 50 mg every six hours for three doses. The doses are arranged so that the patient receives the last dose one hour before the test, along with 50 mg of diphenhydramine intramuscularly.

Conclusion

Due to the increased use of radiographic contrast materials in imaging procedures (such as enhanced computerized axial tomography) more untoward reactions of this nature might be expected. Proper treatment mandates that epinephrine in proper dosages be administered immediately. Other modalities should be instituted early in treatment of these conditions, such as administration of intravenous fluids, oxygen, and antihistamines with careful monitoring of the patient's vital signs.

When radiographic contrast materials must be administered to make the diagnosis of life-threatening illness or injury and the patient has a past history of serious reaction to such materials, corticosteroids may be given prophylactically.

Acknowledgments

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Consultation

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For the past 30 years the need for teaching continuity of care and management of the ambulatory patient increasingly has concerned faculties of medical schools. Various teaching programs instituted in a number of schools have been reported in the literature, notably by Reed[1] and by Sanazaro and Bates.[2]

Reed and Jantz[3] discussed an evaluation of the first year of a recent program at the University of Maryland School of Medicine. This article discusses the modification, evolution, and current state of that program from 1970–71 through 1983–84.

Curriculum in Ambulatory Care

JULIAN W. REED MD

Dr. Reed is Coordinator, Ambulatory Care Curriculum; Associate Professor of Medicine, Family Medicine, Epidemiology and Preventive Medicine; and Assistant Professor of Clinical Psychiatry, University of Maryland School of Medicine; Medical Director, John L. Deaton Medical Center. Reprints: Bressler Research Building, 655 West Baltimore Street, Baltimore, Maryland 21201.

In September 1969, the Faculty Board of the University of Maryland School of Medicine voted for a mandatory eight-week course for all senior students in the comprehensive care of ambulatory patients. Those in favor believed that teaching using the ambulatory patient (which occurred primarily in the outpatient clinics of the University of Maryland Hospital) was uneven and in many ways deficient.

A primary reason was that admitting privileges to the University of Maryland Hospital were granted to part-time faculty if they volunteered to work at least one day a week in one of the outpatient clinics. Ostensibly, these part-time faculty were to teach junior and senior medical students. A limited number of the preceptors were both qualified and interested in teaching. In addition, there were no determined or stated curricular objectives for students or faculty, and there was no identified core curriculum. There was significant variation among preceptors and clinics in method and content of teaching.

The faculty realized that 70 to 80 percent of the medicine practiced in this country is on ambulatory patients. However, at that time the major emphasis on teaching in the senior year centered on inpatients. The faculty concluded that teaching about the ambulatory patient in our medical school was deficient. Those in favor of the mandatory eight-week ambulatory rotation hoped its implementation would correct these deficiencies and raise the quality of teaching with reference to the ambulatory patient (outpatients) to the level of teaching concerned with inpatients.

Development

An Ambulatory Care Curriculum Committee was appointed by then Dean John Moxley MD under the chairmanship of John Young MD. The Committee met monthly for a year. The author served on the Committee representing the Department of Preventive Medicine. Ultimately he was asked and agreed to serve as program coordinator of the Ambulatory Curriculum.

Under the Curriculum Committee, three objectives and a core curriculum were developed. Appropriate sites were selected, with emphasis placed on interest and qualifications of preceptors who would teach at each site. To assure the quality of teaching would remain consistently high, it was stressed that the primary responsibility of the preceptors was to fulfill their teaching obligation; patient care was secondary. Each student was assigned a primary preceptor for each clinic session, and a back-up preceptor always was available.

The program began on June 5, 1970 and included three community pediatric centers, a neighborhood comprehensive health center, and four community hospitals, in addition to the University of Maryland Medical Clinic, and the University of Maryland Family Practice Clinic. Initial financial support came from a Medical School Improvement Grant. None of the locations involved received financial remuneration from the Medical School, except those sites designated as Area Health Education Centers (AHEC) from 1980–83. The AHEC ambulatory sites received partial financial support from the Medical School during the period of the AHEC grant.

Chart A shows the class size and percentages of males and females from the first year (1970–71) to the year just concluded (1983–84). As class sizes increased, the number of ambulatory sites were increased to accommodate all the students in their senior year, since it is a mandatory rotation. For the first year, 10 sites were involved; in 1983–84, 17 sites were required.

The major teaching emphases by discipline have been Adult Medicine, Pediatrics, Family Medicine, and since 1980, Geriatrics. Sometimes a combination of two or more disciplines is taught at a location. Chart B (next page) lists the sites, disciplines taught, and number of students accommodated per eight-week rotation during

Chart A. University of Maryland Senior Classes 1970–71 to 1983–84

Year	Number of Males	Percentage of Class	Number of Females	Percentage of Class	Total Class Size
1970–71	119	94	8	6	127
1971–72	118	87	18	13	136
1972–73	128	83	28	17	116
1973–74	117	85	20	15	137
1974–75	105	88	15	12	120
1975–76	121	87	18	13	139
1976–77	120	84	23	16	143
1977–78	106	74	44	26	150
1978–79	121	79	34	21	155
1979–80	137	82	31	18	168
1980–81	124	74	44	26	168
1981–82	133	81	33	19	166
1982–83	129	77	39	23	168
1983–84	119	75	43	25	162
Total number of graduates					2,095

Chart B. Ambulatory Care Curriculum 1983–84

Name of Site	Disciplines Taught	Number of Students Accommodated per Rotation
1. Waxter/V.A. Fort Howard	Geriatrics	2
2. Cumberland AHEC	Adult Medicine	3
3. St. Agnes Hospital	Adult Medicine & Emergency Room	1
4. Deaton Harbor Health Care Center	Geriatrics	1
5. Family Health Center	Adult Medicine & Pediatrics	2
6. GBMC Community & Family Health Center	Adult Medicine & Pediatrics	2
7. Maryland General	Adult Medicine, Geriatrics & Emergency Room	4
8. Mercy	Adult Medicine	4
9. Mercy	Pediatrics	2
10. Pediatric OPD	Pediatrics	2
11. Rosemont Community Doctors Center	Adult Medicine & Pediatrics	2
12. South Baltimore General	Adult Medicine, Pediatrics & Emergency Room	4
13. University CPC	Pediatrics	4
14. West Baltimore Community Health Center	Adult Medicine & Pediatrics	2
15. York Hospital	Adult Medicine	2
16. University Health Center (College Park)	Medicine	1
17. Union Memorial	Adult Medicine & Emergency Room	2

1983–84. Over the past six years, a two-week Emergency Room experience has been available at several sites. This experience has been especially well received by the students, who believe it contributed significantly to their knowledge of the management of medical or surgical emergencies of the ambulatory patient.

Although the Faculty resolution stipulated the course be of eight-weeks' duration, it was not possible to fully implement this until 1976–77. Before that time, there were two weeks each of Anesthesiology, Radiology, and Ophthalmology in the senior-year curriculum. Consequently, from 1970–75, the Ambulatory Care Curriculum was a six-week rotation.

Objectives

The objectives of the Ambulatory Care Curriculum have remained unchanged. They are presented to each student in a letter and elaborated on at orientation, the first day of the rotation.

1. To enable the senior student to learn and apply the principles of coordinated and comprehensive care to outpatients, including *prevention* and *rehabilitation* as well as adequate diagnosis and appropriate therapy of individuals with medical and/or psychiatric illnesses.
2. To enable the senior student to learn how to function effectively as a member of a health team, within the hospital complex as well as in the community, interacting constructively with other physicians, social workers, public health nurses, rehabilitation counselors, and other members of the health professions.
3. To enable the senior student to become familiar with public and private agencies in the community that can provide such specialized service and/or consultation for patients and their families that is not available within the hospital complex. (To accomplish this objective, students are expected to visit these agencies when it is feasible or relevant and discuss the patient and/or family with a representative of that agency.) Students are encouraged to use the problem-oriented medical record whenever possible to assist them in fulfilling these objectives.

Since the course has become an eight-week rotation, there are five rotations during the senior year, each with 32 to 36 students. Even though it is a mandatory course, students are allowed as much leeway as possible in selecting where they will take their rotation. Halfway through the junior year each student is given a booklet containing a description of each ambulatory site, which includes salient features of location, hours of clinic, types of patients seen, names of principal preceptors, and any information that would make the site unique. Before a prearranged date, students select five clinics for each of the five rotations in order of preference. A computer then matches students and locations. About 80 to 90 percent of the students are matched with their first or second choices. The remainder are usually matched with third or fourth choice. No student has been assigned to a location not listed as a choice. The theory has been that students generally will apply themselves better and learn more if they have input into the selection of the ambulatory site.

Students meet three times as a group: for orientation, for feedback midway through their rotation at a stu-

dent-faculty luncheon, and for a final critique and summarization on the last day of the rotation.

Orientation

The first group meeting is the orientation session, the first morning of the rotation. The objectives of the curriculum, previously mailed to the students along with their assigned locations, are reviewed in detail.

To give students some idea of what to expect at the new learning site, comments made by the previous group of students (both favorable and unfavorable) are read. These comments were recorded from the students at the student-faculty luncheon, held midway through the previous rotation and completed on the last day of that rotation. Potential pitfalls are identified along with positive aspects of the learning possibilities at each site. Particularly knowledgeable and effective preceptors are identified by name, along with those whose ability and teaching skills are not as well developed, at least in the previous students' perceptions. Armed with this information, the students beginning a rotation have the basic facts necessary to make maximum use of the learning potential available at each site.

It is emphasized to the students that in their meeting with their principal preceptor later that day, the back-up preceptors for each clinic session should be identified to them. The sine qua non of successful teaching/learning in the ambulatory setting requires that the patient, the patient's medical record, the student, and the preceptor all be together at the same time.

To assist students in meeting the objectives of the course, it has been helpful to show two slides and discuss their content. Figure 1 is shown to conceptualize the students' role in understanding the total patient, that is, the physical (medical), psychological, social, and vocational factors in evaluation and treatment of that individual (see Objective 1). It is pointed out to students that in order to determine the patient's physical functioning status (Section A), the evaluating physician, seeing the patient for the first time, takes a careful history, performs a thorough physical examination, and orders the appropriate laboratory studies, x-rays, and specialty consultations to substantiate or exclude diagnostic impressions. Students then discuss diagnostic and therapeutic plans of action with preceptors. When the results are integrated students have a good idea of the patient's physical functioning status.

Following students' six-weeks' experience in the Brief Therapy Clinic (a psychiatric outpatient clinic in the Institute of Psychiatry and Human Behavior) they are qualified and capable of performing and determining the functional evaluation of the patient's personality (Section B). Students also are asked to determine, by

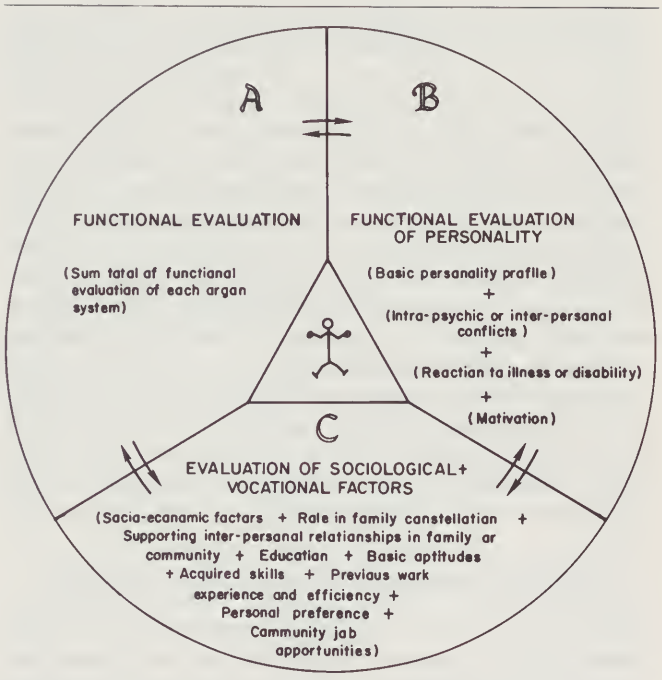


Figure 1. The Total Patient Concept

carefully interviewing the patient, whether there might be significant intrapsychic or interpersonal conflicts predisposing to or aggravating the patient's physical symptoms. After one or two meetings with the patient, and particularly if the medical evaluation fails to disclose any structural or organic pathology, students have a reasonably accurate impression of the patient's psychological functioning, and how or if it is interacting with the patient's physical symptoms.

Evaluation of the sociological and vocational factors (Section C) is emphasized as essential to students if they are to accurately and appropriately diagnose (understand) and treat (rehabilitate) their patients, if rehabilitation is necessary. Many patients derive significant benefit from one or two meetings if all parameters of their current situations are analyzed and understood. The frequent interaction and overlapping between sections A, B, and C is emphasized. They are almost interdependent.

Students thus are helped to deal with all facets of each patient's life each time he or she is seen. This approach may take extra time initially but ultimately saves time and expense and enhances the possibility the student (physician) will make a more accurate diagnosis sooner. This is different from the more traditional approach where the patient is evaluated as if he/she were a collection of organ systems.

Figure 2 is a conceptualization of the students' role as key members (evaluating physicians) of an interdisciplinary health care team. In this capacity (see Objective 2) they interact with other members of the clinical team to determine the functional capacity of patients, physically (medically), psychologically, socially, and vocationally. If the patient is so incapacitated he/she is unable to work, it may be necessary for the evaluating physician (as coordinator for the patient) to interact with other members of the community team, such as the Division of Vocational Rehabilitation, to help rehabilitate the patient. Although it is seldom necessary to involve many members of both the clinical and community teams, when a patient has complex medical and emotional problems, this approach is most apt to be successful in diagnosis, treatment, and rehabilitation.[4] Students are encouraged to communicate and cooperate with other members of the health care team.

Questionnaire I (Core Curriculum)

Early in the first year of curriculum 1970–71 each preceptor was asked to submit at least two questions on any subject related to an ambulatory patient, the answers to which they thought senior students should know by the end of the rotation. Questions generally were essays intended to stimulate the student's observation and thinking about total patient care and the team approach. Questions required technical information from different disciplines (medicine, psychiatry, nursing, clinical pharmacy, nutrition, and vocational rehabilitation). More philosophical questions challenged the student in solving the clinical problem outlined. Students were told to imagine themselves alone in their own office with patients presented to them. They were told their responses should be medically sound and clinically appropriate as well as practical and realistic.

During 1970–71, students were required to respond to all of the 60 questions. Each year the questionnaire was revised. During 1983–84, the questionnaire contained 90 questions; students were required to respond to 60 of the 90 questions (Chart C). Four mandatory questions were included because their responses were thought to contain important information for the student, or the responses were thought essential in monitoring the quality and content of the course (as perceived by the students) from one rotation to the next.

Students were told to read through the questionnaire on day one and to begin to organize their reading and study on questions about which they lacked sufficient information and knowledge. Two textbooks were recommended to the students for at least reference, if not purchase. The first was *Primary Care Medicine: Office Evaluation and Management of the Adult Patient*;[5] the second, *Principles of Ambulatory Medicine.*[6]

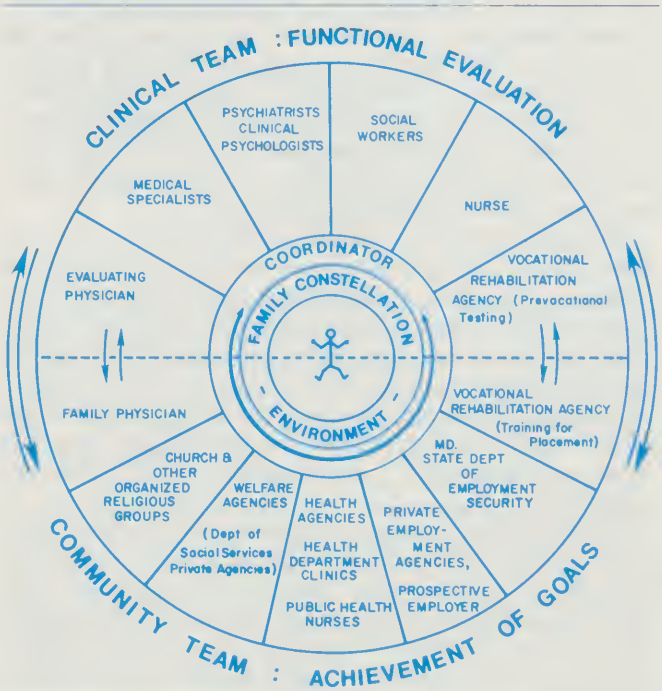


Figure 2. Rehabilitation—the Team Approach

Student Evaluation

The final portion of orientation relates to how students are evaluated in the course. To help preceptors evaluate the students more uniformly and to assist

Chart C. Breakdown by Discipline of Questions in Core Curriculum Questionnaire I (1983–84)*

Medicine	21
Pediatrics	20
Psychiatry (psychology)	10
Geriatrics	7
Rehabilitation	7
Miscellaneous (religion, ethics, patient compliance, etc.)	6
Social Work	4
Preventive Medicine	3
Nursing	3
Nutrition	3
Clinical Pharmacy	2
Mandatory	4
TOTAL	90

* A copy of Questionnaire I is available on request.

students in fulfilling the course objectives, 18 questions were developed. Copies of these questions are given to both preceptors and students at the beginning of the rotation.* These questions were intended to stimulate the student to best use the learning potential at each clinical session as well as to challenge the student to function in a responsible and professionally mature manner. Typical questions are: Did the student learn how to integrate basic science knowledge into consideration of the total patient, the disease process, and the relevant psychological, social, and vocational factors involved? Did he/she show evidence of improvement in clinical judgment (ordering diagnostic studies, prescribing medications, etc.)? Was the student able to establish rapport with the patient?

Students were informed they should strive to function in their clinical setting so they honestly could respond affirmatively to all 18 questions. They were encouraged to read through the questions from time to time during the rotation and to focus their attention on those questions to which they could only respond negatively. Students have perceived these questions as challenging them in their emotional and professional growth and maturity.

Students are expected to spend all their time at designated sites except for Tuesday and Thursday afternoons. For the first six weeks of rotation they are required to attend seminars at the University under the sponsorship of the Department of Epidemiology and Preventive Medicine. These seminars apply preventive medicine principles to the ambulatory patient. During the last two weeks of rotation, the seminars are under the sponsorship of the Department of Rehabilitation Medicine and include topics relevant to pediatric and adult patients. Alternative learning experiences are available for students taking ambulatory rotations out of town.

Student-Faculty Luncheon

As mentioned, each rotation is divided evenly, and two faculty-student luncheons are held during the fourth week, halfway through the rotation. Attendance by faculty is encouraged, but for students, it is mandatory. A representative from the Division of Vocational Rehabilitation describes the agency, its goals, objectives, and stresses that any individual age 16 to 70 who is a resident of the state with a physical, intellectual, or emotional disability that would interfere with substantial, gainful activity is eligible for the services the agency can provide. It is pointed out that physicians are the greatest source of referrals, and that services are available nationwide. Students are encouraged to make appropriate referrals to the agency in their future practice of medicine.

The remainder of the luncheon is tape recorded. Each student gives a two to three minute critique summarizing impressions of his/her learning experience (favorable or unfavorable) during the first four weeks. This includes types of patients seen, quality and consistency of the teaching and supervision, and any suggestions for improving the learning experience. Following each critique, the coordinator makes whatever comment or suggestion is relevant or pertinent. In this manner, if a student is not having a good learning experience, it is recognized and appropriate changes can be made. In the majority of instances, minor problems can be resolved by conferences between students and preceptors. When more serious problems are identified, or if conferences fail to resolve the problem, the coordinator and preceptor try to settle the dispute to the satisfaction of both parties. On rare occasions it has been necessary to change students in the middle of a rotation. It is stressed to students that adjusting to different styles and techniques of teaching is a valuable part of their learning experience. On rare occasions it has been necessary to replace a preceptor.

Following the students' presentations, preceptors are called on to make any necessary or appropriate comments. Both students and preceptors think the luncheons are a worthwhile opportunity to hear what is going on at other locations. Frequently the learning potential of a location is improved by applying and integrating techniques and formats from other ambulatory sites. The student-faculty luncheon also provides the coordinator with an up-to-date, verbatim picture of the type of experience each student is having.

Private Office Experience

At this luncheon, the coordinator reminds students that 70 to 80 percent of the medicine practiced in the country deals with the ambulatory patient usually seen in the physician's office. He encourages students to spend at least one afternoon or evening session or a full week with a primary care practitioner in his/her own office. This can be a preceptor from the clinic, a relative, a friend, acquaintance, or physicians from the family health clinic willing to supervise students in their office practices. This is a practical experience for the student, adding a dimension not available in a clinic site.

In the private office setting, students observe how the office is organized and staffed, the type of medical record used, how the physician manages time, how he/she arranges for hospital or home visits and for evening, weekend, and vacation coverage and so on. Virtually all

* Copies available on request.

students availing themselves of this private practice experience over the past 14 years found it to be of some value.

Final Session

The final session is on the morning of the last day of the rotation. Its purpose is twofold. During the first 15 to 20 minutes of the meeting, students are asked to complete Questionnaire II, a Program Evaluation Questionnaire. This contains fifty objective questions, to be answered with a "yes," "no," or one sentence, if possible. Its content is relatively unchanged since it was first used in 1970–71.

The fifty questions can be grouped into five categories: (1) program operation, (2) teaching effectiveness, (3) philosophy of the program, (4) attitudes and morale, and (5) specific disciplines. A summary of the evaluation of the first year 1970–71, including an in-depth analysis of Questionnaire II was published in this *Journal* in 1974.[7] Since copies of this questionnaire are sent to each location at the end of each rotation, any deficiencies perceived by the students are immediately brought to the attention of the preceptors. Corrective changes, if necessary, can be made immediately. This close monitoring assures that quality teaching is maintained at each site for each eight-week rotation.

After Questionnaire II has been completed, students are asked to give a final critique of their experiences, emphasizing any positive or negative changes that have occurred since the recorded comments at the student-faculty luncheon held halfway through the eight-week rotation. If final comments differ from comments made by the students at the luncheon, they are communicated to the group of students beginning the next rotation.

Students usually are pleased with the experience. For most of them, it is the first time in their medical curriculum they have been the first physician to see the patient and, consequently, to have primary responsibility for diagnosis and treatment. In most junior clerkships, at least one house officer has evaluated and begun treating patients who are assigned to him/her.

Annual Preceptors' Luncheon

An annual preceptors' luncheon is held during the second week of June following the completion of the last rotation and before the beginning of the next academic year. Attendance of all preceptors is encouraged and is required for at least one preceptor from each site.

The luncheon is held to review the previous year's experience from the preceptor's point of view and to discuss suggestions or possible methods of improving the learning experience for the students at each site. These sessions are also tape recorded, edited for clarity by the coordinator, and sent to the preceptors who attended the meeting as well as those who were not present. Each preceptor gives impressions of the previous year's five eight-week rotations, commenting on students' attitudes, preparedness, motivation to learn, and overall functioning in the clinic setting. When problems regarding student performance (either individually or collectively) are identified they are discussed candidly.

The coordinator has the opportunity to convey to the preceptors any logistical or other concerns students may have voiced during the previous year. The atmosphere is open and cordial; stimulating discussion is held regarding methods and technique of teaching. The two most common themes from preceptors are that first, they enjoy teaching senior students in this setting because they are usually willing, able, and motivated to assume significant responsibility for patients, and second, preceptors frequently are able to observe significant improvement in student's clinical skills and professional growth during the rotation.

New questions are submitted by the preceptors for possible inclusion in Questionnaire I for the following year. Based on recommendations from the preceptors, obsolete questions are deleted and ambiguous questions are clarified.

The luncheon usually concludes with the coordinator emphasizing that the primary function of the preceptor is to teach the student in a one-to-one relationship.

From the beginning, there never has been a shortage of locations or preceptors. Turnover among preceptors has been relatively slow, with the majority teaching for several years. Academic appointments are given to qualified preceptors by the appropriate Departmental Chairman, that is, medicine, family medicine, or pediatrics.

Responsibilities of the Coordinator

The primary responsibility of the coordinator is to provide good learning experiences for every senior student at each site for each of the five eight-week rotations held in the senior year. This requires close monitoring of every student's experience during each rotation.

The second responsibility of the coordinator is to determine whether the three objectives of the curriculum are met by the student. The coordinator is assisted in this determination by the letter grade (A to F) given to the student by his/her preceptor in the clinic. The standard School of Medicine Student Evaluation form contains, in addition to a letter grade, space for a

summary statement about the student that preceptors are required to complete. Failing grades or incompletes must be rectified prior to graduation. This remedial work requires the approval of the Dean of Student Affairs, the Coordinator, and the preceptor.

For the coordinator to determine to his own satisfaction that course objectives have been met satisfactorily, he reads all the students' responses to the 60 questions on Questionnaire I since this contains the knowledge and information the student should have on completion of the course. Based on the content of responses, the coordinator sends each student written comments identifying errors and acknowledging well-thought-out responses. Students appreciate this written response to their completing the mandatory questionnaire.

Summary: Coordinator's Impressions

Feedback from the majority of the senior students who have completed this mandatory eight-week course is that it provides an integral, significant, and relevant part of the medical school curriculum. Admittedly, there are many different ways of teaching about the ambulatory patient, one or more of which might be superior to the present curriculum. However, I believe the students' perception of this course is essentially correct for these reasons:

1. The volume of patients is such (one new patient with 3 to 5 follow-up patients during the average ambulatory session) that time provides opportunities to integrate the basic sciences with the clinical sciences.
2. Sessions also provide the senior student a unique opportunity to interact with and learn from other allied health professionals: nurses, social workers, clinical pharmacists, nutritionists, and so on.
3. The student has an opportunity to recognize and deal appropriately with the most common chronic illnesses seen in ambulatory patients: hypertension, diabetes, various types of arthritis, chronic obstructive pulmonary disease, and neuromusculoskeletal disorders.
4. Students have opportunities to learn when and if acute hospitalization is necessary.
5. The usual rotation enables students to be able to recognize and treat appropriately (medically and psychologically) patients with physical symptoms that may be predisposed or aggravated by unresolved emotional conflicts. Students also learn to recognize and treat the common psychiatric problems usually seen in the ambulatory patient, that is, depression, anxiety, and psychophysiologic disorders. Students learn when and if a referral to a clinical psychologist or psychiatrist is indicated.

Taken together, the above reasons usually result in a significant growth in the senior student's professional competence during the rotation, specifically his/her clinical skills.

Concomitantly, almost all students report a significant increase in their professional confidence at the end of their ambulatory rotation. They generally feel more comfortable and secure in their ability to deal appropriately and successfully with the usual ambulatory patient in medical, psychological, economic and vocational aspects.

Peer Review

The course was first reviewed in 1978 by a faculty committee composed of full-time faculty, chaired by Juan Granados MD. Only those sites within the University complex under the direct control of full-time faculty were reviewed. It received a favorable evaluation and was cited for its effective leadership, good organization, and close monitoring. Both students and committee believed the eight-week length of the course was appropriate and that any reduction in its duration would be detrimental to one of the most important goals of the rotation: the long-term follow-up of patients in an ambulatory setting.

The course was again reviewed by a committee of full-time faculty in 1983–84, a subcommittee of the Clinical Years Committee. It was chaired by Peter Hartmann MD. During this peer review, only extramural sites were reviewed. The course again received an overall favorable evaluation. The committee concluded that the course should continue to be mandatory, to remain in the senior year, and to be of eight-weeks duration. The peer review committee also recommended that a standing Advisory Committee be formed to assist the coordinator. It further recommended that each ambulatory site should have a review every two years by full-time faculty. The recommendations of the peer review committee were given to the Committee for Curriculum Coordination, chaired by George Balis MD. This Committee made additional recommendations of its own, primarily regarding administrative reorganization and governance and presented them to the Acting Dean, Marjorie Wilson MD. Until this time, the course was administered and coordinated through the Dean's Office, but on 1 January 1985, the course came under the direction of a committee composed of five designated representatives of the Departments of Internal Medicine, Family Medicine, Pediatrics, Epide-

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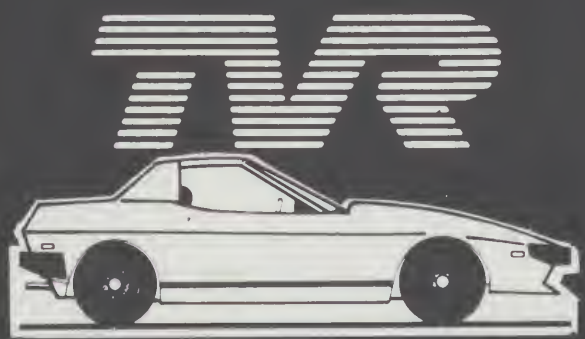
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miology and Preventive Medicine, and Rehabilitation Medicine. The chairman of the committee (coordinator of the course) will rotate among the departments of Internal Medicine, Family Medicine, and Pediatrics and will serve for two years.

The course in ambulatory care is now well established as an integral part of the senior medical school curriculum. The recent changes in administration and governance should enable it to continue at its present level and may enhance the quality of the content of the course in the future.

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High-pressure injection injuries are well known to industrial medicine specialists, but other physicians, especially in emergency care, should be aware of this hazard.

High-Pressure Tool Injection Injuries

MICHAEL A. McCLINTON MD and STEWART WRIGHT MD

The authors are at the Raymond Curtis Hand Center, Union Memorial Hospital, Baltimore, Maryland.

Paint guns, grease guns, and hydraulic lines may cause high-pressure injection injuries. Nozzle-tip pressure ranges from 1,500 to 12,000 pounds per square inch (see Figure 1). Fluid may exit the pinpoint nozzle at a velocity in excess of 600 feet per second. A variety of fluids are used including paint, paint thinner, diesel oil, grease, cleaning fluid, lubricating oil, and rustproofing material.

The first case reported was by Rees in 1937, and since then more than 150 cases have appeared in the medical literature.

Significance of Injury

The importance of early recognition of this injury cannot be overemphasized. In recent years two such cases have ended with legal action against the treating physician. Each involved a patient examination by a junior member of a medical team; the seriousness of the injury was missed. Both patients eventually required amputation of the digits.

The usual presentation is a male who has been employed using high-pressure tools for less than six months. While trying to clear the nozzle tip with his nondominant index fingertip, he accidentally discharges the pressure gun. (Note: the nozzle does not need to touch the hand for injury to occur.) When he presents to the emergency department or family physician he has a pinpoint entry wound on the volar aspect of his finger and may have some swelling proximally in the digit (see Figure 2). He may not complain of much pain for the first few hours after injury because of compression of digitial nerves. If the significance of the injury is not appreciated, the patient may be given a tetanus shot, sent home, and told to soak the digit. He will not be seen again until 24 hours later when he returns with intense pain and swelling. The index finger of the nondominant hand is the most common digit



Figure 1. High pressure paint gun.



Figure 2. Small entrance wound belies seriousness of underlying digital injury.

involved, followed by the long finger and palm.

The degree of injury depends on the type, amount, and extent of dispersal of the injected material. Turpentine is the most destructive agent followed by lead-based paint and diesel oil. Grease and latex paint are least toxic. Paint injections to rats demonstrated that paint injected under low pressure caused an inflammatory reaction similar to but not as extensive as comparable fluid injection through a high pressure gun. Saline solution injected through a high pressure device caused a minimal inflammatory response. This study supports the concept that the inflammatory reaction results from direct toxicity of the injected material.

Acute effects are related to two factors: chemical inflammatory reaction, especially with turpentine and mineral spirits, and sequelae of ischemia. The ischemia is secondary to increased pressure in the finger. Discoloration and numbness soon after the injury imply a serious prognosis. Under no circumstances should a digital anesthetic block be used as this may produce further local swelling and vasospasm. Warm soaks also should be avoided, as this may increase swelling. The site of injection is important prognostically: digital injuries usually are more severe than those in the palm. This is because of the greater area available for dispersion of material in the palm.

Treatment

The appropriate treatment of these injuries includes initial recognition of their severity. Most will require hospital admission and intensive medical and surgical treatment. These patients should receive tetanus toxoid and intravenous antibiotics.

All cases should have radiographs of the involved hand because lead-based paints and grease may be visible on x-ray films to provide an estimate of the extent of proximal spread (see Figure 3). Subcutaneous emphysema also may be visible on x-ray films. Injection usually occurs near the tip of the finger, however, fluid penetrates quickly along the fascial planes, neurovascular bundles, or tendon sheaths. It may spread into the palm or forearm and has been found proximally as far as the elbow following an injection into the palm.

Once recognized, the recommended treatment is decompression of the digit and removal of the injected material in the operating room. There is no place for debridement in the emergency room with a potentially dangerous local anesthetic block of the base of the digit. Exposure is through a midaxial digital incision. An arm tourniquet is used to provide a bloodless field. Thorough exploration extending proximally to wrist and forearm and dorsally to extensor retinaculum is necessary at times as is meticulous irrigation with a jet lavage to dislodge adherent material. The use of paint thinners or oil solvents is not recommended as these may cause further tissue destruction.

The tendon sheaths are opened to determine whether material has penetrated these spaces. Any necrotic fat must be excised, neurovascular bundles decompressed, and, if there is excessive swelling, dorsal incisions also may be needed to release the intrinsic muscle compartments. Wounds are left open for later secondary closure or skin grafting. Intravenous corticosteroids have been recommended but recent consensus is that they are not helpful.

Sequelae of these injuries may include residual stiffness, cold intolerance, dysesthesia, and pain of the involved digit. Frequently amputation is necessary, especially when the fluid is lead-based paint and if treatment has been delayed. Some reported series have a 60 percent amputation rate when paint has been injected.



Figure 3. Radiograph shows extent of paint penetration in the finger.

The length of time from injury to treatment is another determinant, and the results become much worse with a delay greater than 12 hours. On occasion primary amputation is indicated, particularly when the index finger is involved.

High-pressure injection injuries may appear innocuous when first seen, but they have the potential to cause loss of digits. The primary care physician should be aware of the possible sequelae of these injuries and should refer patients for appropriate treatment. Physicians also need to cooperate with industry in educating workers of the hazards high-pressure tools and hydraulic lines may pose.

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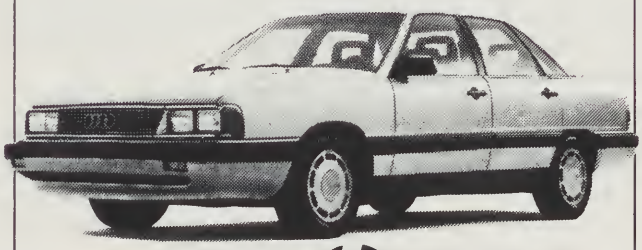
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Medical Miscellany

Med-Chi's Photo Contest

The Annual Photo Contest, one of the more popular activities of the Medical and Chirurgical Faculty's Annual Meeting, is once again in progress. All members of the Faculty and its Auxiliary (except professional photographers) are invited to enter an original photo for this year's judging.

Winners of the 1985 Photo Contest will be selected by Michele Elliott, Assistant Director of the Dalsheimer Gallery and Ed Wortek, Instructor of Photography at Goucher College. This year's contest chairman is Jerrold M. Post MD, winner of last year's contest in both the black-and-white and color categories.

An exhibit of all competing photos will be on display April 25 and 26 at the 1985 Annual Meeting. Contest winners will be announced at the Meeting and their photos reproduced in the *Maryland Medical Journal.* Gift certificates from the Dalsheimer Gallery will be awarded the first and second place winners in each category.

To be included in this year's judging, photos must be mailed or brought to the Medical and Chirurgical Faculty office at 1211 Cathedral Street, Baltimore, Maryland 21201 by 5 p.m. on **Friday, March 29, 1985.** Photos **will not** be returned by mail but may be claimed at the exhibit area on the afternoon of FRIDAY, APRIL 26 or the morning of SATURDAY, ARPIL 27, 1985. Any photos not collected at that time will be available at the Faculty office thereafter.

Full contest rules may be found elsewhere in this issue. Anyone needing more information may contact Diane Sakwa at Med-Chi (539-0872 in Baltimore; 1-800-492-1056 toll-free in Maryland).

• • •

Volunteers Needed for Hearing Loss Study

People with otosclerosis, a familiar form of deafness marked by abnormal bone growth in the ear, are needed to evaluate a drug that may prevent progressive hearing loss.

Participants must have diagnosed otosclerosis, be more than 18 years old, and, if female, be using adequate birth-control methods. All will receive free hearing and blood tests every six months for two years at The Johns Hopkins Medical Institutions.

Otosclerosis occurs in an estimated 240 of 100,000 people and is the most common cause of progressive hearing loss, other than aging, in the adult population. It is about twice as common in women as in men.

For more information, call 301-955-8505.

Baltimore Rh Lab Seeks Antibodies

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If any of your patients have red cell antibodies and would be eligible to become a plasma donor, you may refer them to the Rh Typing Laboratory at 539-4321. The donor will be monetarily compensated.

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1987 Semiannual
Mid-September
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September 14–18
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Your Medical Faculty at Work

At its January 10, 1985 meeting the Executive Committee approved the 1985 budget for recommendation to Council. Approval was also given to two nominees for the Medical Advisory Board, Motor Vehicle Administration.

Various other actions and approvals were given on recommendations to the Council.

• • •

At its first 1985 meeting, Council approved a $1,650,000 budget for the year. The majority of the funding for this budget comes from membership dues, which have remained the same for several years.

Council also, in accordance with authority granted it by the House of Delegates, voted an expenditure of up to $2,000,000 to cover the estimated costs of renovations of the present Faculty building and the former School #49, located immediately south of the Faculty building. A contract for renovations in the amount of $1,768,290 was approved. This was the lowest bid as well as the shortest time proposed for completion of the work. A fund-raising proposal was approved for raising additional funds to complete this project.

Council authorized publicizing to the memership that the UQCPRO Committee is acting as recipient of reports of any adverse reactions occurring to patients covered by the newly publicized PRO regulations. Data should be sent to the Faculty Office for referral to this committee.

Approval was given for holding the 1987 Semiannual Meeting in Hawaii. Faculty leadership was granted approval to hold an annual retreat.

Council reconsidered its November action in connection with inspection of free-standing abortion facilities. The action had approved conducting inspection of such facilities to ensure minimum standards. Because of legal implications involved, the Council rescinded its previous support.

Various Professional Ethics opinions were approved. They are as follows:

Disclosure of Office Policies

A physician's office of any type (private, walk-in clinic, etc.) should disclose in a reasonable fashion its contractual limitations to patients or potential patients at the earliest possible moment. Such limitations would include: payment policies, representative fees, office hours, type of care rendered and types of insurance accepted.

Payment for Services Rendered by Two or More Physicians

.01 When one physician covers for another, only one physician may bill for the services rendered. Double billing is strictly forbidden.

.02 The bill should clearly inform the patient of the exact medical services included in the bill, the date these services were provided, and whether those services were consultative or direct care.

.03 When two or more physicians working in partnership or professional association call on each other for consultation, the medical necessity for such consultation should be clearly documented. If a pattern appears of consultations requested when apparently not medically necessary, peer review action may follow.

X-rays and Charges for Transfer

Ownership The physician who creates the patient's medical records is the owner of those records. AN X-RAY IS PART OF THE MEDICAL RECORD. However, if the physician is associated with some type of a legal or corporate entity, the records may be the property of that entity, depending upon the terms of the relationship. If a written agreement concerning the custody and ownership of the medical records exists, such an agreement prevails. It is in the physician's best interests to enter into such an agreement.

Transfer between Physicians The patient's interests are paramount when dealing with a request for transfer of medical records. Physicians who are in possession of a patient's medical records should not refuse, for any reason, to make copies of those records promptly available to the current treating physician upon the receipt of the patient's proper written request. Copies of pertinent medical records or an abstract thereof should not be withheld pending payment of a patient's outstanding account. If additional information is required, the physician should respond courteously and promptly. If the copying or abstraction is unduly burdensome or lengthy, a reasonable fee may be charged. Such a fee should be agreed upon at the outset. A physician who is planning to retire should, likewise, send medical records to physicians free of charge; medical records of former patients should not be sold. WHEN TRANSFERRING X-RAYS TO THE CURRENT TREATING PHYSICIAN, THE PHYSICIAN IN POSSESSION OF THE X-RAY MAY CHARGE THE REASONABLE COST OF COPYING AND POSTAGE. UNDER NO CIRCUMSTANCES MAY A DEPOSIT (REFUNDABLE OR NON-REFUNDABLE) BE CHARGED FOR LENDING THE X-RAY TO THE CURRENT TREATING PHYSICIAN.

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Cardiology	9	2	0
Dermatology	1	2	0
Emergency Medicine	18	4	2
General/Family Practice	33	17	4
Internal Medicine	88	14	5
Neurology	1	1	0
Obstetrics/Gynecology	12	4	1
Occupational Medicine	4	2	0
Ophthalmology	5	2	0
Orthopaedics	4	6	2
Otolaryngology	1	3	0
Pathology	4	1	0
Pediatrics	26	5	2
Psychiatry	7	3	3
Radiology	5	0	0
Surgery	18	6	1
Urology	5	3	0
*Part time	24		

* Part-time "physicians available" refers to physicians interested in finding part-time positions, locum tenens, etc. Part-time "positions available" refers to positions within the particular specialty that are less than 40 hours per week. We have general part-time positions such as monitoring of blood donors, working in a drug abuse center.

PHYSICIAN PLACEMENT SERVICE

The Medical and Chirurgical Faculty of the State of Maryland maintains a Placement Service for the convenience of Maryland physicians, hospitals and communities in search of candidates for positions available in our state. A detailed description of such opportunities should be forwarded to the Physician Placement Service, 1211 Cathedral St., Baltimore, MD 21201; telephone 1-301-539-0872.

Physicians wishing to locate in Maryland are invited to submit a resumé to be kept on file with the Physician Placement Service. Candidates are requested to inform the Faculty when they are no longer available for consideration for opportunities which might be available in Maryland.

Journal announcements on the Classified Advertising page for Physician Placement Service are charged at the regular Classified Advertising rate.

Information for Authors

Med-Chi members reading papers before organizations are invited to submit their papers to the MMJ for consideration for publication.

The *Maryland Medical Journal* is the monthly publication of the Medical and Chirurgical Faculty of the State of Maryland. Its goals are educational and informative: the publishing of scientific articles and other technical information as well as editorials, special articles (evaluations, position papers, reviews of nonscientific subjects), membership news, notices of medical events, legislative and governmental news, meetings, continuing education courses, and programs and policies of the Faculty.

Manuscripts may be sent to Editor *MMJ*, 1211 Cathedral St., Baltimore, MD 21201. Articles are accepted for publication on the condition that they are contributed solely to this journal. Transmittal letters should designate one author as correspondent and include his/her address and telephone number. Manuscripts are reviewed by the editor, editorial board members, and guest reviewers. The final decision is reserved for the Editor.

Specifications

Manuscripts must be original typed copy, double-spaced throughout (including text, case reports, legends, tables, and references) with margins of at least one inch. Number pages consecutively. Please submit two additional copies.

Include in the manuscript the concise title, full name of the author (or authors) with highest degree, academic and professional titles, affiliations, and any institutional or other credits.

An introductory synposis/abstract of approximately 100–150 words is required.

Tables are to be typed on separate sheets of paper, numbered, and have a brief descriptive title. The Editor reserves the right to edit tables. Be sure that statistics are consistent in both tables and text.

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Illustrations are material that cannot be set in type. Photographic material must be submitted as high-contrast, glossy prints. Drawings and graphs must be done professionally in india ink on high-grade white drawing paper. *Omit illustrations that do not increase understanding of text, and limit them to a reasonable number.* Four or fewer illustrations should be adequate for a manuscript of 4 to 5 typed pages. Legends are to be typed on a separate sheet of paper. Type on a gummed label and affix to the back of each illustration: figure number, title of manuscript, name of senior author, and arrow indicating top. Legends for illustrations should be typed on a separate page with numbers corresponding to those on the photographs and drawings. *Cost of printing color photographs must be borne by the author.*

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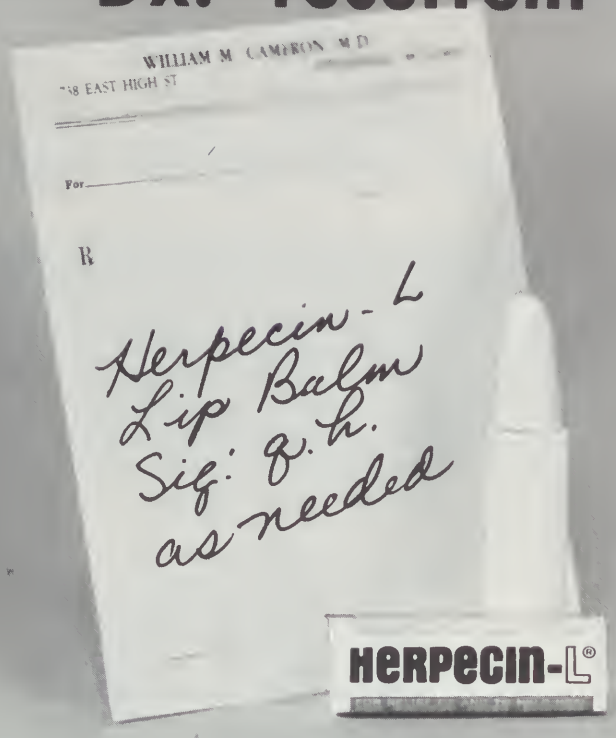
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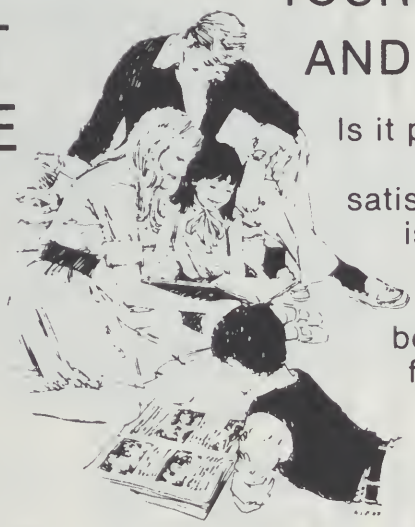
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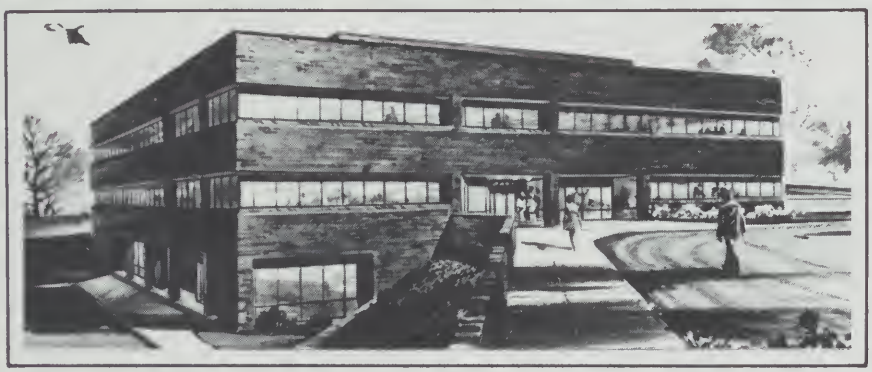
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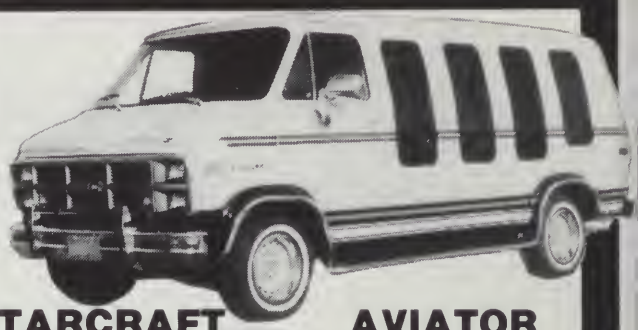
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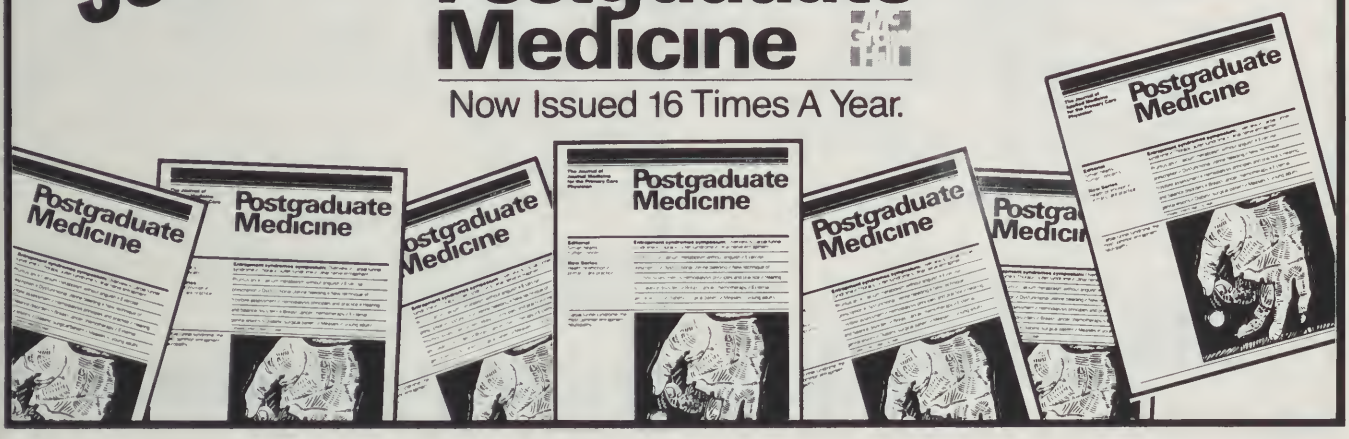
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Mar 23–24 Hemodynamic Monitoring/Patient Care and Pulmonary Artery Catheterization, sponsored by the Department of Anesthesiology and Critical Care Medicine. Fee: $350; 12.5 AMA Cat I credits. Info: P. Nulle (301-955-6046).

Apr 10–11 Topics in Ambulatory Medicine, at the Hyatt Regency Baltimore. Fee: $295, $150 for residents and fellows; 17 AMA Cat I credits. Info: P. Nulle (301-955-6046).

Apr 11–12 Eleventh Annual Symposium on Diagnosis and Treatment of Neoplastic Disorders: Medical, Surgical & Radiotherapeutic Aspects, at the Oncology Center. Fee: $225 (includes social activities); 16 AMA Cat I credits. Info: Prog. Coord. (301-955-6046).

Apr 16–17 Asbestos: The Workplace, Buildings and Schools—Risk Assessment and Management. Fee: $300; 16 AMA Cat I credits; continuing education units; ABIH certification. Info: C. Kearney (301-955-5880).

Apr 20 Current Concepts in Thyroid Disease. Fee: $90; 9 AMA Cat I credits. Info: D. Heydinger (301-955-6046).

Continuously throughout the year: One-week Microsurgery Training Course, Basic techniques and principles, individualized instruction, and practice sessions. Fee: $1,200; 40 AMA Cat I credits. Info: Prog. Coord. (301-955-3169).

The Department of Radiology and Radiological Science, offers several courses in abdominal and obstetrical ultrasound: courses scheduled Jan 14 to Dec 6, 1985. Info: Joan Mosmiller, Department of Radiology (301-955-8450).

Basic Practicum—June 3–7; Aug 5–9; Sep 23–27. Fee: $460; 40 AMA Cat I credits.

Advanced Practicum—May 13–17; Dec 2–6. Fee $460; 40 AMA Cat I credits.

Visiting Physicians offered weekly throughout the year for experience in the lab and participation in reading sessions. By appointment. Fee: $460; 40 AMA Cat I credits.

Advanced Obstetrics and Gynecology course designed for obstetricians who have been using real time ultrasound. Apr 15–17; Nov 18–20. Fee: $325; 24 AMA Cat I credits.

Diagnostic Ultrasound in Obstetrics and Gynecology course given annually attracts world's leading experts in the field of obstetrical and gynecology ultrasound. Sep 12–13, 1985; 16 AMA Cat I credits.

The Johns Hopkins Medical Grand Rounds. Accredited audiovisual subscription program for the practicing physician. 40 AMA Cat I credits/year. Write to the Johns Hopkins University School of Medicine, Office of Continuing Education, 720 Rutland Ave., Baltimore, MD 21205 (301-955-3988).

Clinical Cytopathology for Pathologists, 1985 Postgraduate Institute: March to May 1985, Home Study Course A; **May 6–17,** In-Residence Course B at the Johns Hopkins Medical Institution, Baltimore. Designed solely for pathologists who are Certified (or qualified for certification) by the American Board of Pathology or its international equivalent, this is an intensive refresher in all aspects of the field of Clinical Cytopathology. Topics are covered in lectures, in small informal conferences, and over the microscope. Self-instructional material is available. Loan set of slides with texts (Course A) will be sent to each participant within the U.S. and Canada for home study during March and April before Course B in Baltimore. Special arrangements to study Course A must be made by participants outside the U.S. and Canada. 152 AMA Cat I credits. *The entire course given in English.*

Completed preregistration must be accomplished before **April 5, 1985,** unless by special arrangement. Info: John K. Frost, MD, 604 Pathology, Bldg., The Johns Hopkins Hospital, Baltimore, MD 21205, USA.

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University of Maryland School of Medicine

CME Courses: For each course additional information may be obtained by contacting Program of Continuing Education, University of Maryland School of Medicine, Room 300, MSTF, 10 South Pine St., Baltimore, MD 21201 (301-528-3956).

Mar 14–May 4 Advanced Immunology. Baltimore. 15 AMA Cat I credits; info (301-528-3956).

Mar 14–28 Selected Topics in Family Practice: Spring Series. Baltimore. Fee $25/session; 3 consecutive Thursday evenings; 7.5 AMA Cat I credits.

Mar 24–29 Fifth Annual Postgraduate Course in Neurological Disorders: Stroke and Tumors, Paradise Island, The Bahamas. Fee $425; 25 AMA Cat I credits.

Apr 12–13 First Annual University of Maryland Contact Lens Symposium. Columbia Inn. Fee: $165; 11.5 AMA Cat I credits.

May 3–4 Contemporary Issues in the Diagnosis and Management of Chronic Congestive Heart Failure. Baltimore. Fee: $170; 10 AMA Cat I credits.

Jun 17–18 Symposium on Perinatal Endocrinology. Baltimore. Fee: $150; 14 AMA Cat I credits and 14 ACOG cognates.

June 23–28 Eleventh Annual Family Medicine Review Course, Ocean City. Fee: $350.

June 27–29 Dermatology Days, Ocean City. Early fee: $230; 11.25 AMA Cat I credits.

Oct thru May—Visiting Practitioner Preceptorship Program. CME experience on full-time clinical basis in choice of discipline; 5 days to 6 weeks. Hour-to-hour AMA Cat I credits.

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Miscellaneous Meetings

Apr 12–14 Evaluation and Psychotherapeutic Planning and Intensive Short-Term Dynamic Psychotherapy—a Comprehensive Audiovisual Symposium, sponsored by the American Institute for Short-Term Dynamic Psychotherapy, Washington, DC. 17 CME Cat I credits. Info: J. Worchel MD, 1020 East Jefferson, Charlottesville, VA 22901 (804-296-3777).

Apr 19–21 Emergency Medicine for the Primary Care Physician, sponsored by the Office of Continuing Medical Education, the Medical College of Virginia. Fee: $250; 16.5 instruction hours. Info: K. Martin (808-786-0494)

Apr 22–24 NIH Consensus Development Conference: Anesthesia and Sedation in the Dental Office. NIH Clinical Center, Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Info: Murphy, Prospect Associates, Suite 401, 2115 E. Jefferson St., Rockville, MD 20852 (301-468-6555).

Apr 25–28 Annual Meeting, The Virginia Society of Otolaryngology-Head and Neck Surgery, Tides Inn, Irvington, VA. Info: D. Strawdermann, 4205 Dover Rd., Richmond VA 23221 (804-353-2721)

May 8 Disability and the Social Security Administration. CME topic of the American Medical Women's Association. Meeting held at the Johns Hopkins Faculty Club, Homewood Campus; cash bar at 6:30 p.m.; dinner at 7 p.m.

May 8–11 Annual Meeting, The Virginia Society of Ophthalmology, Boar's Head Inn, Charlottesville, VA. Cosponsored by University of Virginia Ophthalmology Dept. Info: D. Strawderman, 4205 Dover Rd., Richmond, VA 23221 (804-353-2721)

May 8–12 Annual Meeting and Scientific Session of the Maryland Academy of Family Physicians, Ocean City. Fee: $100 (members), $150 (nonmembers). Info: J. Zebley MD, Program Chairman (301-659-0640).

May 15–17 Update in Infectious Diseases, Philadelphia. Info: Registrar, American College of Physicians, 4200 Pine St., Philadelphia, PA 19104.

Jun 5–7 Current Concepts in Oncology and Hematologic Malignancies, Philadelphia. Info: Registrar, American College of Physicians, 4200 Pine St., Philadelphia, PA 19104.

Jun 10–12 Consensus Development Conference on Electroconvulsive Therapy. NIH Clinical Center, Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Info: M. Dillon, Prospect Associates, Suite 401, 2115 East Jefferson St., Rockville, MD 20852 (301-468-6555).

Jun 16–21 Eighth Annual Eastern Shore Medical Symposium, Rehoboth Beach, DE. Sponsored by Jefferson Medical College, The Medical Society of Delaware, University of Delaware. 29 AMA Cat I credits. Info: S. Brocka, University of Delaware, Wilcastle Center, 2800 Pennsylvania Ave., Wilmington, DE 19806 (302-573-4400).

Aug 4–9 An Intensive Review of Internal Medicine, Jefferson Medical College in cooperation with the University of Delaware. 45 Cat I AMA credits. Info: S. Brocka, University of Delaware, 2800 Pennsylvania Ave., Wilmington, DE 19806 (302-573-4400).

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Taylor Manor Hospital CME Lectures

All lectures at 3 p.m. in the Psychiatric Center at Taylor Manor Hospital, Ellicott City, MD unless otherwise indicated. Info: Taylor Manor Hospital, College Ave., Ellicott City, MD 21043 (301-465-3322)

Mar 20 Psychopathology of Young Women (Psychosomatic Aspects)

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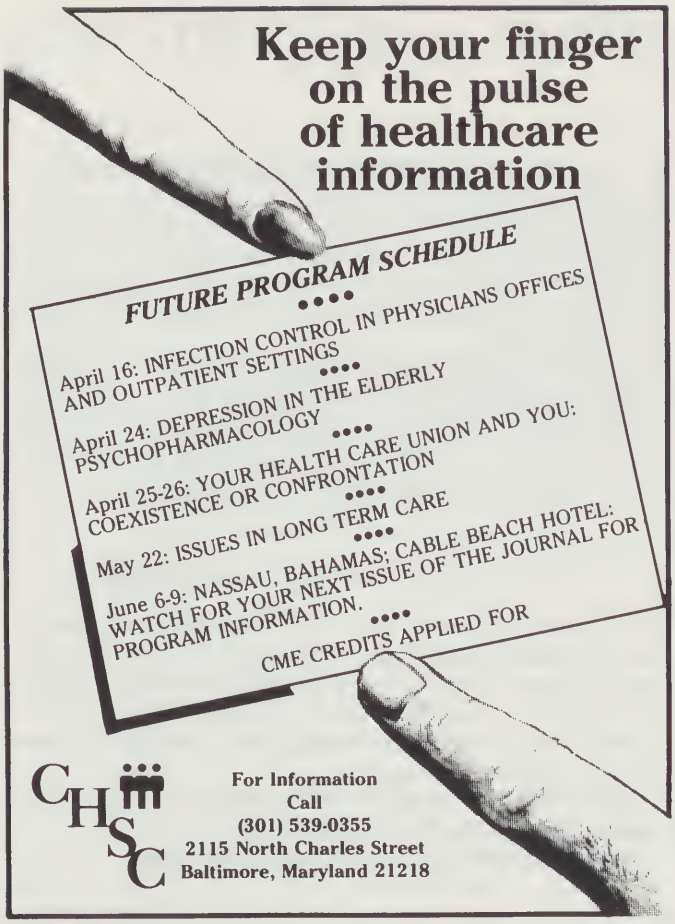
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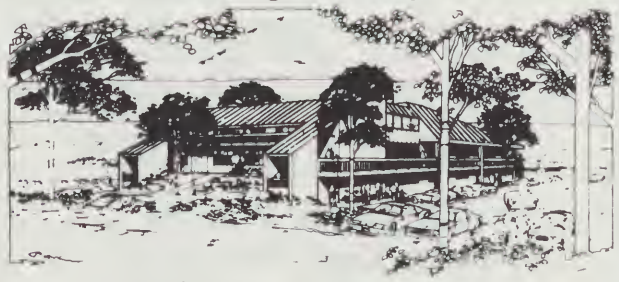
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Rafael Alfonso MD, PA 304
Allstate Leasing, Inc. 215
American Office 215
April Day Studio 294
Associated Speech and Language Services 291
Beethoven/Riehl Estate Management 215
Biostim, Inc. 206
Bonnie Ridge Apartments 306
Bon Secours Professional Center 218
Business Automation, Inc. 300
BTR Realty, Inc. 304
Campbell Laboratories 296
Cellular One 212
Consultative Examinations, Inc. 305
Creative Health Seminar Consultants 304
Curtis 1000 Information Systems 214
CTS 273
Diagnostic Assay Services 207
Dockside Charter Services 294
Eastman Kodak 227
Elkridge Estates 307
Fallston General Hospital 305
Family Home Care 300
Family Recovery Center 291
Freestate Management Co. 297
Gladding Leasing Inc. 298
GMC Truck 298
Gordon & Heneson PA 272
Gundry Hospital 251
Heron Harbour Isle 221
Hidden Brook Treatment Center 208
Intracare Corp. 222
Jerry's Toyota 211
King's Grant 204
Joel R. Kruh Esq. 304
Lewis Medical Instruments 210
Eli Lilly 216
Liquid Luxury 298
Management Information Systems Corporation 296
Marion Laboratories 257
Maryland Army National Guard 306
Maryland Medical Laboratory 203
Maryland Office Systems 247
Med-Chi 288, 300
Medical Mutual Liability ..... cover 2, 252
Michaelson Motors, Inc. 288
MICRO Age 254
Miller Studio 307
Mountain Manor Treatment Center 254
MULTICOM 213
National Credit Management Corp. 247
Oakview Treatment Center 272
Old Court Nursing Center 299
Personal Organization, Inc. 243
PM Baltimore 256
Postgraduate Medicine 299
R & H Motor Cars 217
Roche Laboratories ..... covers 3 and 4
W. James Schiller and Co., PA 243
Schumacher & Seiler, Inc. 209
Sheppard and Enoch Pratt Hospital 280
Sheraton Inner Harbor Hotel 230
E.R. Squibb and Sons, Inc. 237
St. Agnes Hospital 305
Staff Builders 217
Len Stoler Porsche/Audi 291
Strutt Group 217
Stuart Pharmaceutical 271
Sunspace Design Studio 291
Tekmatix NA 305
Towson Valley Motors 308
USAF Recruiting 297
U.S. Army 256
University of Maryland 303
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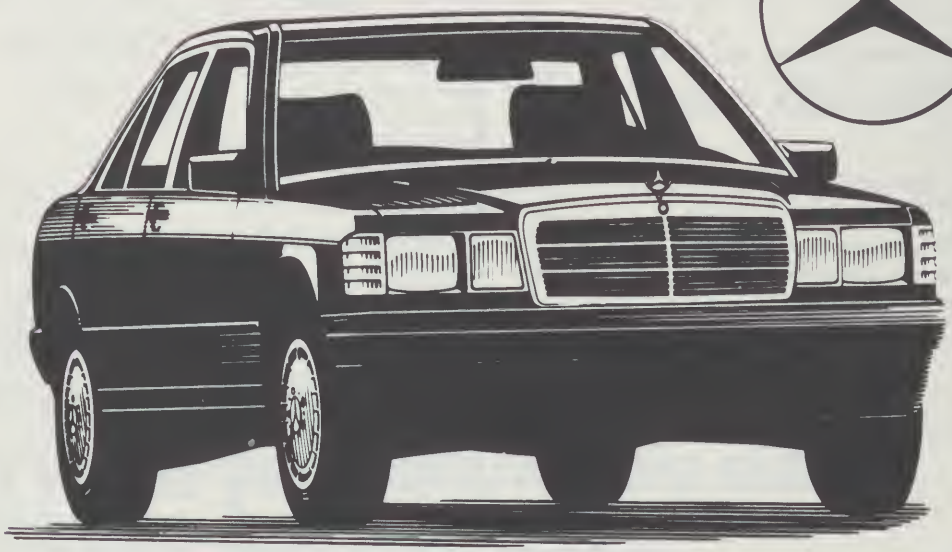
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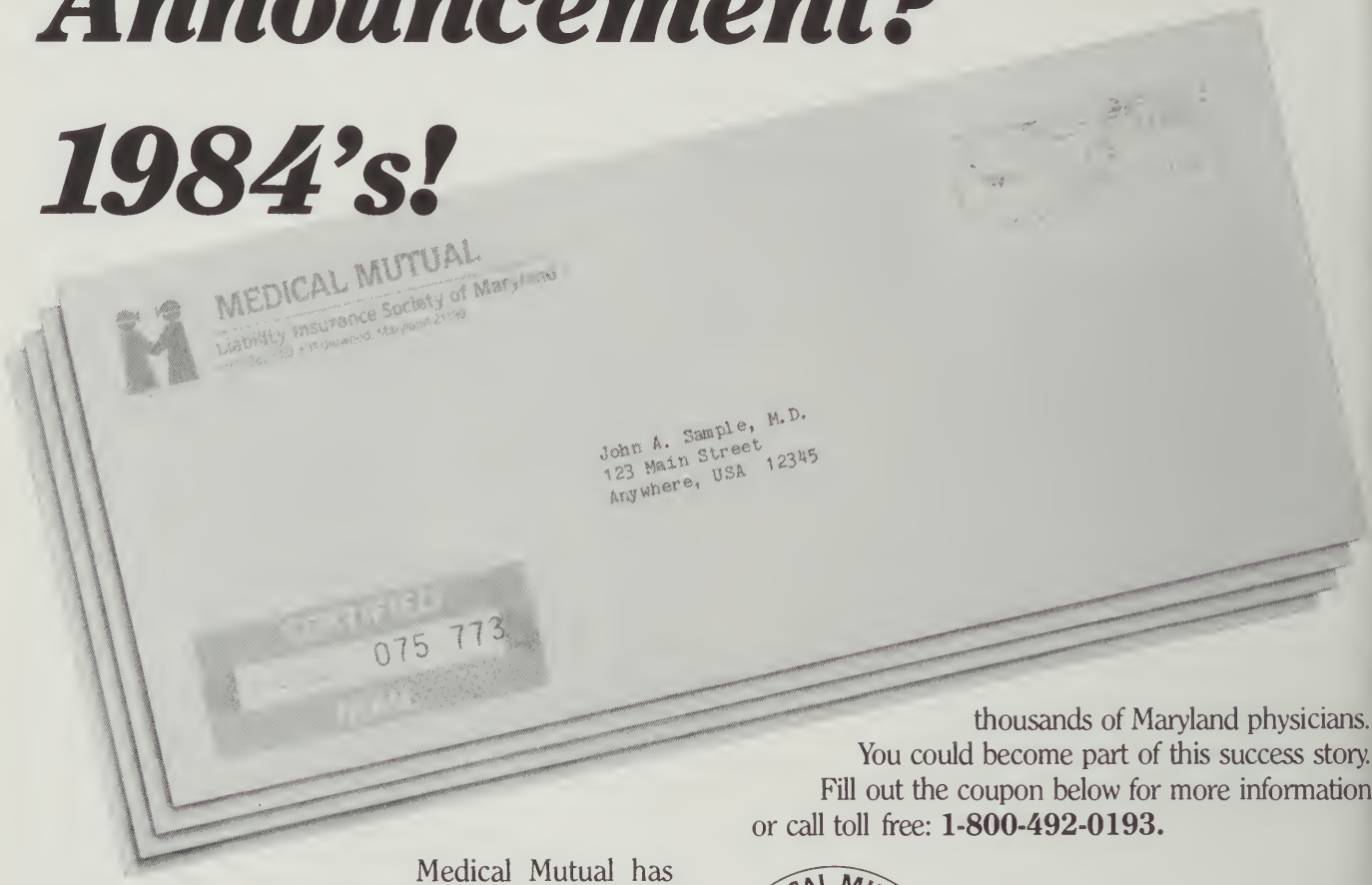


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MISCELLANY

Executive Director's Newsletter 325
Consultation 349
Members in the News 376
Medical Miscellany 377
Change of Address Form 378
Information for Authors 400
Medicolegal Hotline 400
Doctors Take Note 407
Physician Placement Service 408
Classified Ads 411
Advertisers' Index 413

ARTICLES

Cover Story: Let the Show Begin 333

Occult Hemorrhage in a Neonate with Hemophilia A—Fred J. Heldrich MD and Pradeep P. Garg MB 351

Endoscopic Sclerotherapy of Esophageal Varices—David B. Doman MD 355

Editorial: Esophageal Varices—Richard A. Baum MD 357

The Use and Abuse of Cimetidine in a Gastroenterology Clinic—Magaly Rodrigues deBittner PharmD and Frank Iber MD 359

Osteoarthritis VII: Rheumatic Disease in the Elderly—Mary Betty Stevens MD 367

DEPARTMENTS

Annual Meeting Announcements 328

Your Medical Faculty at Work 334

Baltimore County Medical Association 334

The Open Forum 335

The Library Page 338

Disease Control and Epidemiology Newsletter 339

HBP Commentary 347

Maryland Oncology Newsletter 349

One Minute with Diabetes 350

Inside Med-Chi 372

Auxiliary 374

Semiannual Meeting Announcements 387

On the cover: Front detail of old School #49, next door to Med-Chi. More pictures on page 333. (Photo by A. Wintriss)

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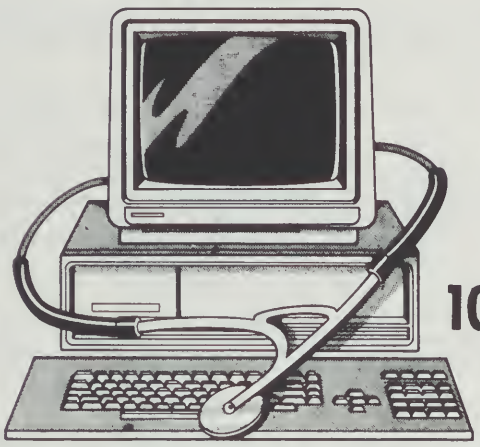
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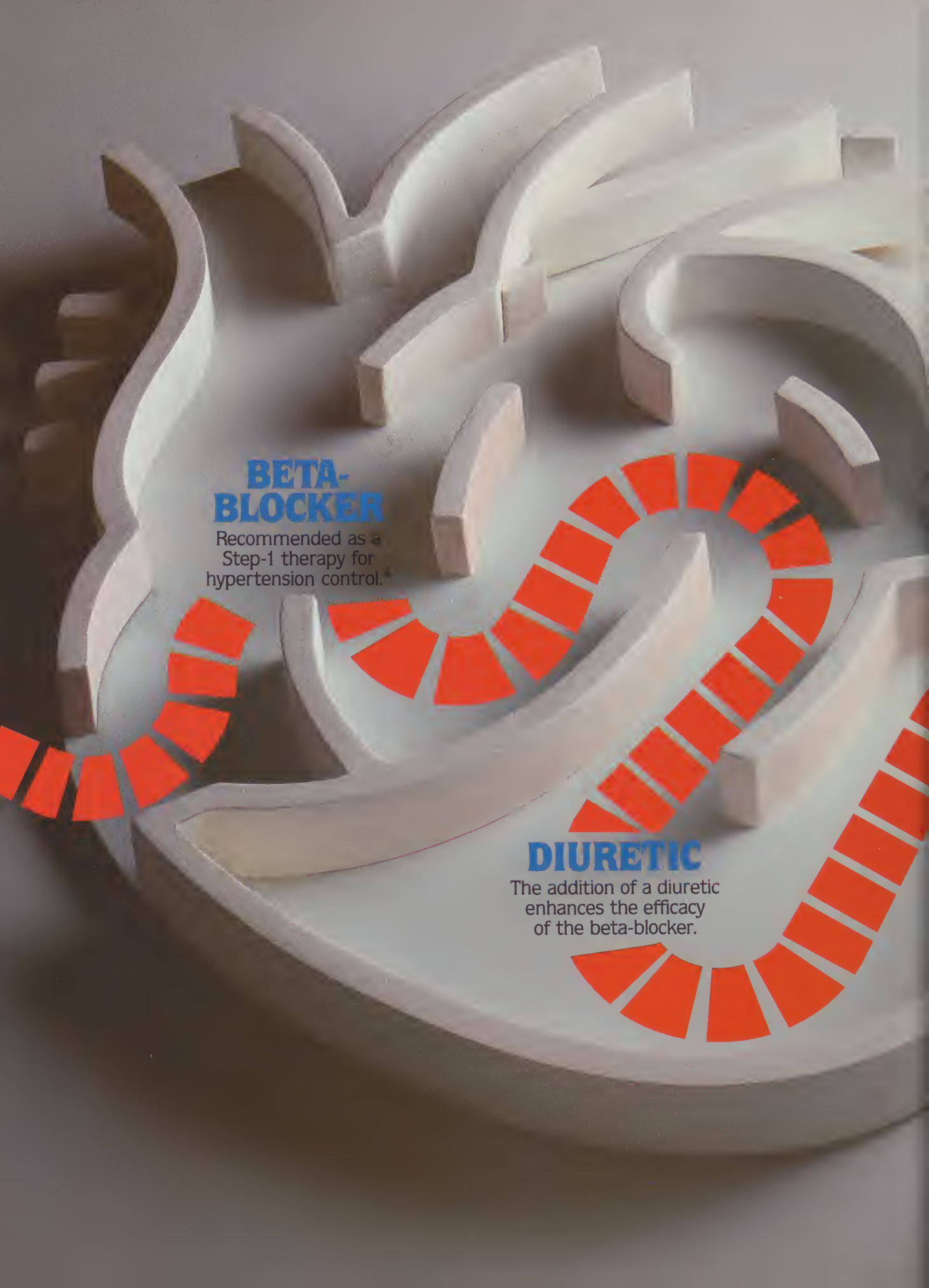
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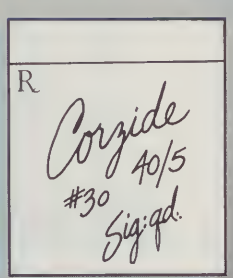
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WARNINGS: Nadolol — Cardiac Failure — Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta-blockade may precipitate more severe failure. Although beta-blockers should be avoided in overt congestive heart failure, if necessary, they can be used with caution in patients with a history of failure who are well compensated, usually with digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle. IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta-blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, digitalize and/or give diuretics, and closely observe response, or discontinue nadolol (gradually, if possible).

Exacerbation of Ischemic Heart Disease Following Abrupt Withdrawal — Hypersensitivity to catecholamines has been observed in patients withdrawn from beta-blocker therapy; exacerbation of angina and, in some cases, myocardial infarction have occurred after *abrupt* discontinuation of such therapy. When discontinuing chronic use of nadolol, particularly in patients with ischemic heart disease, gradually reduce dosage over a 1- to 2-week period and carefully monitor the patient. Reinstitute nadolol promptly (at least temporarily) and take other measures appropriate for management of unstable angina if angina markedly worsens or acute coronary insufficiency develops. Warn patients not to interrupt or discontinue therapy without physician's advice. Because coronary artery disease is common and may be unrecognized, it may be prudent not to discontinue nadolol therapy abruptly even in patients treated only for hypertension.

Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema) — PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA-BLOCKERS. Administer nadolol with caution since it may block bronchodilation produced by endogenous or exogenous catecholamine stimulation of beta$_2$ receptors. **Major Surgery** — Because beta blockade impairs the ability of the heart to respond to reflex stimuli and may increase the risks of general anesthesia and surgical procedures, resulting in protracted hypotension or low cardiac output, it has generally been suggested that such therapy should be withdrawn several days prior to surgery. Recognition of the increased sensitivity to catecholamines of patients recently withdrawn from beta-blocker therapy, however, has made this recommendation controversial. If possible, withdraw beta-blockers well before surgery takes place. In emergency surgery, inform the anesthesiologist that the patient is on beta-blocker therapy. Use of beta-receptor agonists such as isoproterenol, dopamine, dobutamine, or levarterenol can reverse the effects of nadolol. Difficulty in restarting and maintaining the heart beat has also been reported with beta-adrenergic receptor blocking agents. **Diabetes and Hypoglycemia** — Beta-adrenergic blockade may prevent the appearance of premonitory signs and symptoms (e.g., tachycardia and blood pressure changes) of acute hypoglycemia. This is especially important with labile diabetics. Beta-blockade also reduces release of insulin in response to hyperglycemia; therefore, it may be necessary to adjust dose of antidiabetic drugs. **Thyrotoxicosis** — Beta-adrenergic blockade may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism. To avoid abrupt withdrawal of beta-adrenergic blockade which might precipitate a thyroid storm, carefully manage patients suspected of developing thyrotoxicosis.

Bendroflumethiazide — Use with caution in severe renal disease. In patients with renal disease, azotemia may be precipitated. With impaired renal function, effects of the drug may be cumulative. Use with caution in impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma. Sensitivity reactions may occur in patients with a history of allergy or bronchial asthma. Possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

PRECAUTIONS: General — Nadolol — Use with caution in patients with impaired hepatic or renal function (see DOSAGE AND ADMINISTRATION).

Bendroflumethiazide — At appropriate intervals, perform serum electrolytes determination to detect possible electrolyte imbalance warning signs of which are dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and G.I. disturbances such as nausea and vomiting. Observe patients for clinical signs of fluid or electrolyte imbalance; namely, hyponatremia, hypochloremic alkalosis, hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Drugs such as digitalis may influence serum electrolytes. Hypokalemia may develop, especially with brisk diuresis, in presence of severe cirrhosis. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Response of the heart to toxic effects of digitalis can be exaggerated with hypokalemia. Use potassium supplements such as high potassium foods to avoid or treat hypokalemia. Any chloride deficit is generally mild and usually does not require specific therapy except under extraordinary circumstances (as in liver or renal disease). Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction rather than salt administration except in rare instances when the hyponatremia is life threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain thiazide-treated patients. Latent diabetes mellitus may become manifest during thiazide therapy. Antihypertensive effects of bendroflumethiazide may be enhanced in the postsympathectomy patient.

Careful reappraisal of therapy and consideration given to withholding or stopping diuretic therapy is necessary if rising nonprotein nitrogen or BUN (indicative of progressive renal impairment) occurs. Thiazides may decrease serum PBI levels without signs of thyroid disturbance. Thiazides decrease calcium excretion. Pathologic changes in parathyroid gland with hypercalcemia and hypophosphatemia have been occasionally observed with prolonged therapy. Common complications of hyperparathyroidism have not been seen.

Information for Patients — Warn patients, especially those with evidence of coronary artery insufficiency, against interruption or discontinuation of nadolol without physician's advice. Although cardiac failure rarely occurs in properly selected patients, advise patients being treated with beta-adrenergic blocking agents to consult physician at the first sign or symptom of impending failure. Advise patients of proper course if dose inadvertently missed.

Laboratory Tests — Regularly monitor serum and urine electrolyte levels (see WARNINGS, *Bendroflumethiazide*, and PRECAUTIONS, *General, Bendroflumethiazide).*

Drug Interactions — Nadolol — When administered concurrently the following drugs may interact with beta-adrenergic blocking agents: **Anesthetics, general** — exaggeration of anesthetic-induced hypotension (see WARNINGS, *Nadolol, Major Surgery).* **Antidiabetic drugs (oral agents and insulin)** — hypoglycemia or hyperglycemia; adjust antidiabetic drug dosage accordingly (see WARNINGS, *Nadolol, Diabetes and Hypoglycemia).* **Catecholamine-depleting drugs (e.g., reserpine)** — additive effect; monitor closely for evidence of hypotension and/or excessive bradycardia.

Bendroflumethiazide — When administered concurrently the following drugs may interact with thiazide diuretics: **Alcohol, barbiturates, or narcotics** — may potentiate orthostatic hypotension. **Antidiabetic drugs (oral agents and insulin)** — thiazide-induced hyperglycemia may require adjustment of antidiabetic drug dosage. **Other antihypertensive drugs** — additive or potentiated effect. **Corticosteroids, ACTH** — intensified electrolyte depletion, particularly hypokalemia. **Ganglionic or peripheral adrenergic blocking drugs** — potentiated effect. **Preanesthetic and anesthetic agents** — effects may be potentiated; adjust dosage accordingly. **Pressor amines (e.g., norepinephrine)** — possible decrease response but not sufficient to preclude their use. **Skeletal muscle relaxants, nondepolarizing (e.g., tubocurarine)** — possible increased response.

Drug/Laboratory Test Interactions — Discontinue thiazides before tests for parathyroid function (see PRECAUTIONS, *General, Bendroflumethiazide).*

Carcinogenesis, Mutagenesis, Impairment of Fertility — Nadolol — In 1 to 2 years oral toxicologic studies in mice, rats, and dogs, nadolol did not produce significant toxic effects. In 2-year oral carcinogenic studies in rats and mice, nadolol did not produce neoplastic, preneoplastic, or nonneoplastic pathologic lesions. **Bendroflumethiazide** — Long-term studies in animals have not been performed.

Pregnancy — Teratogenic Effects — Nadolol — Category C. In animal reproduction studies with nadolol, evidence of embryo- and fetotoxicity was found in rabbits, but not in rats or hamsters, at doses 5 to 10 times greater (on a mg/kg basis) than the maximum indicated human dose; no teratogenic potential was seen in any of these species. There are no well-controlled studies in pregnant women; therefore, use nadolol in pregnant women only if potential benefit justifies potential risk to the fetus. **Bendroflumethiazide** — Category C. Animal reproduction studies have not been conducted. This drug's effect on the fetus when administered to a pregnant woman or its effect on reproductive capacity is not known. Bendroflumethiazide should be given to a pregnant woman only if clearly needed. **Nonteratogenic Effects** — Since thiazides cross the placental barrier and appear in cord blood, weigh anticipated benefit of the drug in pregnant women against possible hazards to the fetus; these hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other reactions which have occurred in adults.

Nursing Mothers — Both nadolol and bendroflumethiazide are excreted in human milk. Because of the potential for serious adverse reactions in nursing infants either discontinue nursing or discontinue therapy, taking into account the importance of CORZIDE (Nadolol-Bendroflumethiazide Tablets) to the mother.

Pediatric Use — Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Nadolol — Most adverse effects have been mild and transient and have rarely required nadolol withdrawal. **Cardiovascular** — Bradycardia with heart rates of less than 60 beats per minute occurs commonly, and heart rates below 40 beats per minute and/or symptomatic bradycardia were seen in about 2 of 100 patients. Symptoms of peripheral vascular insufficiency, usually of the Raynaud type, have occurred in approximately 2 of 100 patients. Cardiac failure, hypotension, and rhythm/conduction disturbances have each occurred in about 1 of 100 patients. Single instances of first degree and third degree heart block have been reported; intensification of AV block is a known effect of beta-blockers (see also CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS). **Central Nervous System** — Dizziness or fatigue reported in approximately 2 of 100 patients; paresthesias, sedation, and change in behavior reported in approximately 6 of 1000 patients. **Respiratory** — Bronchospasm reported in approximately 1 of 1000 patients (see CONTRAINDICATIONS and WARNINGS). **Gastrointestinal** — Nausea, diarrhea, abdominal discomfort, constipation, vomiting, indigestion, anorexia, bloating, and flatulence each reported in 1 to 5 of 1000 patients. **Miscellaneous** — Each of the following reported in 1 to 5 of 1000 patients: rash; pruritus; headache; dry mouth, eyes, or skin; impotence or decreased libido; facial swelling; weight gain; slurred speech; cough; nasal stuffiness; sweating; tinnitus; blurred vision. Although relationship to drug usage is not clear, sleep disturbances have been reported. The oculomucocutaneous syndrome associated with practolol has not been reported with nadolol. The following adverse reactions may also occur: **Central Nervous System** — reversible mental depression progressing to catatonia; visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss; emotional lability with slightly clouded sensorium, decreased performance on neuropsychometrics. **Gastrointestinal** — mesenteric arterial thrombosis; ischemic colitis. **Hematologic** — agranulocytosis; thrombocytopenic or nonthrombocytopenic purpura. **Allergic** — fever combined with aching and sore throat; laryngospasm; respiratory distress. **Miscellaneous** — reversible alopecia; Peyronie's disease; erythematous rash; arterial insufficiency.

Bendroflumethiazide — Gastrointestinal System — anorexia, gastric irritation, nausea, vomiting, cramping, diarrhea, constipation, jaundice (intrahepatic cholestatic jaundice), pancreatitis. **Central Nervous System** — dizziness, vertigo, paresthesia, headache, xanthopsia. **Hematologic** — leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia. **Dermatologic-Hypersensitivity** — purpura, photosensitivity, rash, urticaria, necrotizing angiitis (vasculitis, cutaneous vasculitis). **Cardiovascular** — orthostatic hypotension may occur. **Other** — hyperglycemia, glycosuria, occasional metabolic acidosis in diabetics, hyperuricemia, allergic glomerulonephritis, muscle spasm, weakness, restlessness. Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy withdrawn.

OVERDOSAGE: Nadolol may cause excessive bradycardia, cardiac failure, hypotension, or bronchospasm if overdosed. Overdosage of thiazides may cause lethargy, which may progress to coma within a few hours, with minimal depression of respiration and cardiovascular function and without evidence of serum electrolyte changes or dehydration. Gastrointestinal irritation and hypermotility may occur. Transitory increase in BUN and serum electrolyte changes may occur, especially in patients with renal impairment.

Treatment — Nadolol can be removed from the general circulation by hemodialysis. In determining duration of corrective therapy, take note of the long duration of the effect of nadolol. In addition to gastric lavage, employ the following measures, as appropriate. **Excessive Bradycardia** — Administer atropine (0.25 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously. **Cardiac Failure** — Administer a digitalis glycoside and diuretic. It has been reported that glucagon may also be useful in this situation. **Hypotension** — Administer vasopressors, e.g., epinephrine or levarterenol. (There is evidence that epinephrine may be the drug of choice.) **Bronchospasm** — Administer a beta$_2$-stimulating agent and/or a theophylline derivative. **Stupor or Coma** — Supportive therapy as warranted. **Gastrointestinal Effects** — Symptomatic treatment as needed. **BUN and/or Serum Electrolyte Abnormalities** — Institute supportive measures as required to maintain hydration, electrolyte balance, respiration, and cardiovascular and renal function.

DOSAGE AND ADMINISTRATION: DOSAGE MUST BE INDIVIDUALIZED. Patients with renal failure require adjustment in dosing interval; see package insert for dosage in these patients.

Consult package insert before prescribing CORZIDE (Nadolol-Bendroflumethiazide Tablets).

HOW SUPPLIED: Available as scored tablets containing 40 mg nadolol combined with 5 mg bendroflumethiazide and 80 mg nadolol combined with 5 mg bendroflumethiazide in bottles of 100.

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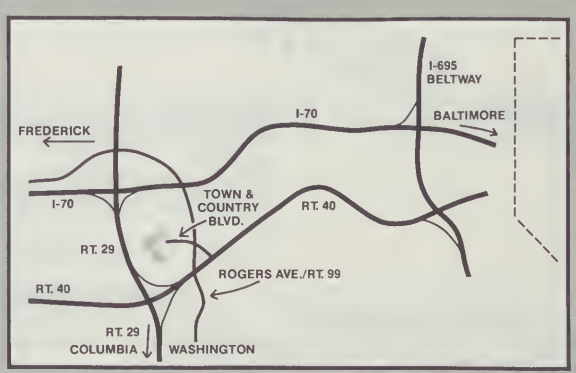


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Executive Director's Newsletter

April 1985

MEDICARE FEE FREEZE UPDATE

Many physicians who do not participate in the Medicare program recently received a letter from Blue Cross/Blue Shield questioning Medicare charges made in the latter part of 1984. This letter is part of an effort to enforce the Medicare regulations that went into effect last October. Under these regulations, nonparticipating physicians may not raise any of their fees to Medicare patients. If you received this letter and you have not increased your fees since June 30, 1984, you should respond promptly and explain that your fees have not increased. If you have raised your fees during this period, consult your attorney about the best way to handle your reply. If you have any questions concerning this letter, contact the Faculty office, 301-539-0872.

RECOGNITION

John H. Hebb, MD, Baltimore County, an AMA Alternate Delegate, was honored recently for recruitment of the largest number of new members into AMA membership. Dr. Hebb received an Honorable Mention certificate.

FEDERAL BUDGET RESTRICTIONS

The proposed 1986 FY federal budget would, among other things, freeze physicians' Medicare payments as well as reduce by half the indirect support of graduate medical education and freeze Medicare payments for resident salaries.

DUAL FEE SCHEDULES

On March 5, 1985, the Commission on Medical Discipline issued a Declaratory Ruling superseding all previous rulings, abolishing the term "Dual Fee Schedules," and setting certain guidelines for fee schedules. The Commission specifically found that physicians could participate in "contractual arrangements with third party payors to provide services at a discounted rate" while charging a higher rate to patients who do not participate in such programs. The Commission also concluded that physicians who do not participate in Medicare can raise their fees to non-Medicare patients.

Accordingly, the maintenance of a multiple fee schedule is no longer illegal; the Commission will now be reviewing each case on an individual basis. Fees charged by physicians, as always, should be based on the amount of time spent and should be within the usual-and-customary range.

We will publish the entire text of the opinion in the May issue of the Maryland Medical Journal. If you wish to have a copy of the opinion before then, please contact Eve Lehman at the Faculty office.

SCHOOL #49 RENOVATION

Renovation of former School #49 to expand the Faculty's headquarters has begun adjacent to the current office. The new building, scheduled for completion in early 1986, will house administrative staff and will include a conference room. The library and the Faculty's billing and computer department will expand their offices in the present building. Renovations to Osler Hall and creation of a new dining room will also be included.

Cost of the total project is approximately $2 million; over half has been pledged. Fund-raising efforts are now under way to secure the remainder. If you are interested in making a contribution to the Faculty's building project, please contact the Faculty office, 301-539-0872 or 1-800-492-1056.

1985 SEMIANNUAL MEETING

We have been able to negotiate an attractive week-long package to Bermuda and, therefore, have changed the dates of the 1985 Semiannual Meeting to Sunday, September 1 - Sunday, September 8. The price of $1,119 per person (double occupancy) includes round-trip airfare on nonstop charter flight from BWI airport, 7 nights at the Southhampton Princess Hotel, breakfast and dinner each day, a 5-hour boat cruise with lunch, transfers between the airport and hotel in Bermuda, baggage handling, taxes, and gratuities. It does not include departure tax or the Registration Fee for the meeting. The meeting dates include the Labor Day Holiday, which means only four regular working days absence from your office. As always, we try to meet all requirements for tax deductibility for the Semiannual Meeting. Watch your mail for the first announcement and registration forms.

BREAST CANCER PAMPHLET

A pamphlet to share with your patients about breast cancer will be available in the near future. Written by a team of physicians working closely with members of the Maryland legislature and the Maryland Women's Health Coalition, it is designed to expand on information given by physicians and to answer some questions concerning the management of breast cancer. A copy will be mailed to each Faculty member; free copies will be available for distribution to your patients.

John Sargeant

Executive Director

CARE HOTLINE FOR IMPAIRED PHYSICIANS - 301-727-0120
HOTLINE FOR EMERGENCY PSYCHIATRIC BEDS - 800-492-0610
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Medical and Chirurgical Faculty of the State of Maryland

187th ANNUAL MEETING

Thursday–Saturday, April 25–27, 1985

HUNT VALLEY INN, HUNT VALLEY, MARYLAND

THURSDAY, APRIL 25, 1985

8:30 a.m.
COUNCIL

9:30 a.m.
HOUSE OF DELEGATES
All members are invited to attend.

8:45 a.m.
LEGISLATION POLICY WITH REGARD TO PHYSICIAN ASSISTANTS, **F. Lynn May,** Arlington, VA and **Curtis Decker,** Annapolis

PRESENT UTILIZATION OF PHYSICIAN ASSISTANTS
Education and Training, Robert Solomon PA-C, Baltimore; **Surgical Physician Assistants, Jeffrey Stark PA-C,** Baltimore; **Physician Assistants Used as Medical Housestaff, Bernard Tabatznik MD,** Baltimore; **Emergency Room Physician Assistants, Wayne S. Barry MD,** Baltimore;

FUTURE ROLE OF PHYSICIAN ASSISTANTS IN THE HEALTH CARE DELIVERY SYSTEM, **James Cawley PA,** Washington DC, **Karl Katterjohn PA-C,** and **Judith H. Schroeter,** Maryland Academy of Physician Assistants

12:15 p.m.
PRAYER LUNCHEON
Pastoral Care: Profession, Plebeian Career, or Placebo? The Reverend Grady F. W. Barbour, Linthicum, Committee on Medicine and Religion/Med-Chi

1:00 p.m.
The Field Liaison for the American College of Surgeons Meeting—All Liaison Fellows and Associate Fellows are Invited to Attend

2:00 p.m.
DEALING WITH THE SOMATIZING PATIENT
Somatization: Diagnosis and Management, Charles V. Ford MD, Nashville, TN; **Somatization: Impact Upon the Patient's Family, Lee Randol Barker MD,** Baltimore, The Maryland Psychiatric Society, Inc.

Emotional Development in the First Eighteen Months: Principles of Intervention and Clinical Diagnosis in Infancy, Serena Wieder PhD, Silver Spring, Maryland Chapter, American Academy of Pediatrics/Infant, Child & Adolescent Health Subcommittee/Med-Chi

Introductory Remarks, Paul Bormel MD, Baltimore; **Joseph S. McLaughlin MD,** Baltimore—**Moderator; Pancreatic Transplantation, Frederick R. Bentley MD,** Baltimore; **Breast Reconstruction After Mastectomy—Immediate versus Delayed, Nelson H. Goldberg MD,** Baltimore; **Application of the Laser to Surgery, William C. Gray MD,** Baltimore, Maryland Chapter, American College of Surgeons

Aneurysmal Subarachnoid Hemorrhage—An Update, Harold P. Adams, Jr. MD, Iowa City, IA, American Heart Association, Maryland Affiliate/Stroke Working Group

The Role of Food Hypersensitivity and Atopic Dermatitis, Hugh A. Sampson MD, Durham, NC, Maryland Asthma and Allergy Society

Endoscopy Update 1985, MD, Washington DC, Maryland Society of Gastrointestinal Endoscopy

Keeping the Elderly Functional and Fit, Franz U. Steinberg MD, St. Louis, MO, Maryland Society of Physical Medicine and Rehabilitation

EFFECTIVE COMMUNICATION CAN REDUCE YOUR RISKS OF MEDICAL LIABILITY, **Marlyn D. Boyd PhD,** Columbia, SC and **Allen Douma MD,** Washington DC, Center for Health Education

4:00 p.m.
PLENARY SESSION
THE CHALLENGE OF CHANGE, **Paul M. Ellwood, Jr. MD,** Excelsior, MN

FRIDAY, APRIL 26, 1985

8:45 a.m.
BREAKFAST AND LEARN

FUTURE PERSPECTIVES OF OTOLARYNGOLOGY—HEAD AND NECK SURGERY
Richard R. Gacek MD Syracuse, NY, Maryland Society of Otolaryngology—Head and Neck Surgery

HELPING YOUR PATIENTS CONTROL THEIR BLOOD LIPIDS
Introduction, Frank Franklin MD, Baltimore; **When and How to Evaluate a Patient's Lipids, Thomas Pearson MD,** Baltimore; **What Can be Learned from a Family History & Apoprotein Measurements, Peter Kwiterovich MD,** Baltimore; **What Diet Should I Recommend? Frank Franklin MD;** Questions and Answers

Break

Introduction, Frank Franklin MD, Baltimore; **How to Help Patients Change Habits and Lose Weight, Kelly Bronwell PhD,** Philadelphia, PA; **Positive and Negative Aspects of Exercise Training: How to Start and Maintain Patients in an Exercise Program, Andrew Goldberg MD,** Baltimore; **How to Help Patients to Stay on Diets in Everyday Life, Ginny Hartmuller MS,** Baltimore; **When and How to Begin Lipid Lowering Medications, Simeon Margolis MD,** Baltimore, American Heart Association, Maryland Affiliate, Inc.

Respiratory Failure and Chronic Obstructive Pulmonary Disease, Peter Terry MD, Baltimore; **Emphysema, Pathogenesis and Future Therapy, Ronald G. Crystal MD,** Bethesda, Maryland Thoracic Society

3rd Annual Meeting of the Directors of Medical Education, Continuing Medical Education Review Committee/Med-Chi

Topic to be Announced, William R. Irby MD, Richmond, VA, Maryland Society for the Rheumatic Diseases/Pfizer Laboratories

10:45 a.m.
The Challenge of Change: Governmental and Socioeconomic Changes in the Health Field, Peyton E. Weary MD, Charlottesville, VA, Maryland Dermatologic Society

Tissue Expanders, John B. McCraw MD, Norfolk, VA, The John Staige Davis Society of Plastic Surgeons of Maryland

THE PHYSICIAN, HIS PATIENT, AND THE WORKPLACE
Post-Coronary By-Pass Patients: Their Ability to Return to Work, Phillip Achuff MD, Baltimore; **Radiology's Role in the Diagnosis of Abestosis, Paul S. Wheeler MD,** Baltimore; **Prescription Medicines: How They Affect the Ability to Work, Michael Spodak MD,** Baltimore, Maryland Occupational Medical Association/Occupational Health Committee/Med-Chi

Legal and Ethical Issues in the Termination of Treatment, Neal M. Friedlander MD, Baltimore, Maryland Lung Association of Maryland

Topic to be Announced, Kenneth H. Williams MD, Ft. Washington, PA, Committee on Physician Rehabilitation/Committee on Alcoholism/Med-Chi

12:15 p.m.
LUNCH AND LEARN

2:00 p.m.
UPDATE ON HIGH BLOOD PRESSURE: 1985
New Drugs and Old Favorites: What to Choose, Ray W. Gifford Jr. MD, Cleveland, OH; **The Five-Hour Office Blood Pressure Check: An Alternative to Hospitalization, Lee Randol Barker MD,** Baltimore; **The New Division of Hypertension: The University of Maryland School of Medicine, Elijah Saunders MD,** Baltimore; **The Role of Calcium, Sodium, and Other Nutrients in Blood Pressure Regulation, Michael J. Horan MD,** Bethesda; **The Systolic Hypertension in the Elderly Program (SHEP), Roger Sherwin MD,** Baltimore; **JNC III: Changes in HBP Referral and Guidelines, Donald O. Fedder DrPH,** Baltimore, Maryland High Blood Pressure Commission

RESOLVING AND AVOIDING MEDICAL STAFF CONFLICTS IN MULTI-SPECIALTY HOSPITALS: A MARKETING APPROACH, **Andrew P. Morley MD,** Decatur, GA and **Ellen J. Belzer,** Kansas City, MO, Maryland Academy of Family Physicians

SPOUSE ABUSE—**Honorable Martha Wyatt,** Annapolis—**Moderator**
Domestic Violence, Honorable John J. Bishop Jr., Towson; **Legal Resources Available to Battered Spouses, L. Tracy Brown, Esquire,** Baltimore; **Why Does She Stay? Harriet Douglas LCSW,** Annapolis; **Medical Aspects of Domestic Violence, Bruce L. Regan MD,** Baltimore; **Clinical Research on Consequences of Criminal Sanctions for Domestic Violence: Implications for Medical Practice and Ethics, Lawrence W. Sherman PhD,** College Park, Office of the Attorney General for the State of Maryland/Med-Chi

DEMONSTRATION OF A MEDICOLEGAL TRIAL INVOLVING TRAUMATIC CHRONIC PAIN SYNDROME
Elliott Fishel MD, Medical Moderator—**H. Albert Korn, Esquire,** Legal Moderator

Physicians
Don M. Long MD, Baltimore, **Paul McAffee MD,** Baltimore, **Godfrey Pearlson MD,** Baltimore, **David Conblath MD,** Baltimore

Judges
The Honorable Robert L. Karwacki, Annapolis, **The Honorable John P. Corderman,** Washington County, **The Honorable John F. McAuliffe,** Montgomery County

Attorneys
Charles M. Tobin, Esquire, Montgomery County, **Stuart M. Salsbury, Esquire,** Baltimore, **John E. Sandbower III Esquire,** Baltimore, **Patti G. Zimmerman, Esquire,** Baltimore, **George J. Goldsborough Jr., Esquire,** Talbot County

Critique
Elliott Fishel MD
William G. Speed III MD
Medicolegal Committee/Med-Chi

Changing Gears to Meet the Challenge of the Geriatric Imperative, William R. Hazzard MD, Baltimore Long Term Care and Geriatrics Committee/Med-Chi

Challenges In Choosing the Best Treatment for the Emotionally Disturbed Adolescent, Jay LeBow MD, Ellicott City, Taylor Manor Hospital

Quality, Technology and Malpractice: Are We Victims of Our Own Devices? William F. Jessee MD, Chapel Hill, NC, Medical Mutual Liability Insurance Society of Maryland

THE HORIZONS OF CHANGE IN ORTHOPEDICS
New Concepts in the Diagnosis and Treatment of Wrist Injuries, Gaylord L. Clark MD, Baltimore; **Michael McClinton MD** Baltimore; **Over the Orthopedic Rainbow, John Gordon MD,** Baltimore, Maryland Orthopaedic Society

4:00 p.m.
Smoking—the #1 Health Problem, Edward N. Brandt Jr. MD, Baltimore, Committee on Preventive Medicine and Public Health/Med-Chi

Acute Post-Operative Hypertension, Leigh Thompson MD, Indianapolis, IN, Maryland-DC Society of Anesthesiologists

APPROACH TO SWALLOWING PROBLEMS: A PANEL DISCUSSION
Neurology, David W. Bucholz MD, Baltimore; **Radiology, Martin W. Donner MD,** Baltimore; **Otolaryngology, Haskins Nashima MD,** Baltimore; **Gastroenterology, William J. Ravich MD, Rehabilitation Medicine, Arthur Siebens MD,** Baltimore, The Johns Hopkins Swallowing Clinic

Bone Imaging in the Study of Pleasure and Pain, Lawrence E. Holder MD, Baltimore, Maryland Society of Nuclear Medicine

SATURDAY, APRIL 27, 1985

8:30 a.m.
Ovarian Echos, Peter L. Cooperberg MD, Vancouver, Canada; **Fetal Intervention, David Graham MD,** Rochester, NY, Maryland Radiological Society/ Obstetrical and Gynecological Society of Maryland

8:45 a.m.
Changing Concepts in Pathology—With Particular Emphasis on Urological Pathology, Fathollah K. Mostofi MD, Washington DC, Maryland Society of Pathologists

PRO: How Will it Affect Your Patients, Everet F. Bryant, Philadelphia, PA; **Leon Kassel MD,** Baltimore; **Bert Harrell,** Baltimore, **Patricia McGuire,** Washington, Public Relations Committee/Med-Chi

10:45 a.m.
PLENARY SESSION
PHYSICIANS AND THEIR FAMILIES
Commonly Encountered Problems in the Families of Physicians, William L. Webb Jr. MD, Baltimore

Panel:
J. D. Drinkard MD, Moderator
Sexual Problems, Emile A. Bendit MD, Baltimore
Issues of Substance Abuse, Sheldon I. Miller MD, Baltimore
Depression and Anxiety, Dean Schuyler MD, Baltimore Sheppard and Enoch Pratt Hospital

12:30 p.m.
MMPAC LUNCHEON
Year of the Doctor: Winners or Losers? The Honorable Larry Young, Chairman House Environmental Matters Committee, Maryland General Assembly

2:00 p.m.
House of Delegates

7:30 p.m.
Presidential Reception and Banquet

MEAL FUNCTIONS

FRIDAY, 8:45–10:15 AM

BREAKFAST AND LEARN

1B. Current Treatment of Epilepsy
Gregory K. Bergey MD, Assistant Professor of Neurology and Physiology, University of Maryland School of Medicine

2B. Biofeedback and Management of Stress Incontinence
Kathryn Larsen Burgio PhD, Senior Staff Fellow, Gerontology Research Center, National Institute on Aging, Francis Scott Key Medical Center

3B. Management of the Frail Geriatric Patient Who is Home Bound
John R. Burton MD, Director, Division of Geriatric Medicine, Francis Scott Key Medical Center

4B. Update on Shock Trauma
Ameen Ramzy MD, M.I.E.M.S.S.

5B. Prenatal Diagnosis of Genetic Disease
Maimon M. Cohen PhD, Professor of Obstetrics & Gynecology and Pediatrics, University of Maryland School of Medicine; Division of Human Genetics, University of Maryland Hospital

6B. Sensible Management of Anemias
C. Lockard Conley MD, Distinguished Service Professor of Medicine, Emeritus, The Johns Hopkins University School of Medicine

7B. Update on Menopause
Gay Guzinski MD, Director, Division of Gynecology, University of Maryland Hospital

8B. Hepatitis Update
Frank L. Iber MD, Professor of Medicine, University of Maryland School of Medicine, Chief, Division of Gastroenterology, University of Maryland Hospital and Baltimore Veterans Administration Medical Center

9B. Commission on Medical Discipline
Hilary T. O'Herlihy MD FACC FCCP, Chairman of the Commission on Medical Discipline

10B. Status of Abortions in Maryland
J. Courtland Robinson MD, Medical Director, Planned Parenthood of Maryland

11B. PPO's
David M. Soloman MD

12B. Update on Migraine
William G. Speed III MD FACP, Associate Professor of Medicine, The Johns Hopkins School of Medicine

FRIDAY, 12:15-1:45 PM

LUNCH AND LEARN

13L. Rheumatic Diseases and Anti-Inflammatory Drugs
Lynn Billingsly MD, Instructor of Medicine, Division of Rheumatology, The Johns Hopkins University School of Medicine

14L. Update on AIDS
Frank M. Calia MD, Professor and Vice Chairman, Department of Medicine, University of Maryland School of Medicine; Chief, Medical Services, Baltimore Veterans Administration Medical Center

15L. Behavioral Pediatrics
Lois T. Flaherty MD, Director, Division of Child and Adolescent Psychiatry, University of Maryland Hospital

16L. Update on Acne
Ronald Goldner MD, Assistant Professor of Dermatology, University of Maryland School of Medicine

17L. Improving Surgical Care of Children
J. Alex Haller Jr. MD, Robert Garrett Professor of Pediatric Surgery, The Johns Hopkins University School of Medicine

18L. Sudden Death Cardiac Arrhythmias
John A. Kastor MD, Theodore E. Woodward Professor of Medicine, Chairman, Department of Medicine, University of Maryland School of Medicine; Physician in Chief, University of Maryland Hospital

19L. Legislative Update
Senator Francis X. Kelly, Member, Senate Budget and Taxation Committee

20L. Use of Drugs in Alcoholic Patients
Michael Potash MD, Instructor of Psychiatry, The Johns Hopkins University School of Medicine; Former Chairman, Governor's Advisory Commission of Drug Abuse

21L. Inflammatory Bowel Disease
David M. Saltzberg MD, Assistant Professor of Medicine, Division of Gastroenterology, University of Maryland School of Medicine

22L. Retirement Planning
Jacques T. Schlenger, Esquire, Managing Partner, Venable, Baetjer and Howard

23L. Sexual Abuse of Children
Charles I. Shubin MD, Chief of Pediatrics, Lutheran Hospital of Maryland, Chairman, Governor's Task Force on Child Abuse and Neglect

24L. PRO—Where it Stands and Where It May Go
Kennard Yaffe MD, Chairman, Baltimore City PSRO; Medical Director, Maryland Foundation for Health Care

RESERVATION FORM

Please detach, enclose in envelope with check. Mail to **Accounting Department,** Med-Chi, 1211 Cathedral Street, Baltimore, MD 21201. Make check payable to Med-Chi. All questions should be directed to Mrs. Mary McGibbon or Ms. M'Lou Schram, 539-0872 or 1-800-492-1056

Everyone who makes a reservation for a meal function is preregistered for the meeting. Please pick up your registration packet which will include your badge, all tickets you have requested, and other pertinent material for the meeting, at the Advance Registration Desk, Rear of the Exhibit Hall, Valley Ballroom, Lower Level, Hunt Valley Inn. **TICKETS WILL NOT BE MAILED.**

No. of Tickets — **Amount**

____ **PRAYER LUNCHEON** $____
Thurs., April 25—12:15 PM.
$13.00 per person

____ **BREAKFAST AND LEARN** $____
Fri., April 26—8:45 AM
$13.00 per person

____ **LUNCH AND LEARN** $____
Fri., April 26—12:15 PM.
$13.00 per person

MY CHOICES OF TABLES ARE: (please assist us by clearly indicating both the number of the tables and the corresponding letter.)

1st _____ 3rd _____
2nd _____ 4th _____

A description of tables is listed elsewhere in the program.

NAME: _____
ADDRESS _____
CITY _____ STATE _____ ZIP _____
TELEPHONE (DAY) _____
COUNTY SOCIETY _____

No. of Tickets — **Amount**

____ **AUXILIARY LUNCHEON** $____
Fri., April 26—1:00 PM
$14.50 per person

____ **MMPAC LUNCHEON** $____
Sat., April 27—12:30 PM
$15.00 per ticket
(If you are a Sustaining member, one ticket will be free. Remember, Sustaining Members are those who pay an additional amount beyond the regular MMPAC dues)

____ **PRESIDENTIAL RECEPTION & BANQUET** $____
Sat., April 27—7:30 PM
If you wish to be seated with specific individuals, please indicate on a separate sheet and attach
$40.00 per person

TOTAL AMOUNT ENCLOSED $____



187th Annual Meeting
Plenary Session

CHALLENGE OF CHANGE

Thursday, April 25th
4:00–5:30 P.M.

Are you concerned about radical changes now under way in the health industry?

Paul M. Ellwood, Jr., MD, President of Interstudy, Inc., will discuss the changes reshaping the health system and the forces behind these changes, describe the medical care firm of the future, and suggest ways for physicians to respond to change during a plenary session, "The Challenge of Change," at the 187th Annual Meeting of the Medical and Chirurgical Faculty of the State of Maryland. The plenary session will be held on April 25, 1985 from 4:00 to 5:30 P.M. at the Hunt Valley Inn.

Dr. Ellwood, a graduate of Stanford University Medical School, is an experienced practicing physician, medical school professor, rehabilitation center administrator, and influential advisor to top policy members in medicine, government, and business.

Dr. Ellwood devised the competitive approach to health delivery reform in the late 1960s. He brought the idea of price competition between health plans (such as health maintenance organizations) to the public's attention and was instrumental in winning government support for a variety of alternative health care delivery systems. Dr. Ellwood more recently contributed to the development of preferred provider organizations and created the MeSH approach to hospital-physician joint ventures. During the plenary session, Dr. Ellwood will focus on the role that competition is playing in reshaping medical care and how it will affect Maryland physicians.

Exhibitors

	Booth Number
Abbott Laboratories	25
Advance Business Systems & Supply Company	218
Air Force Physician Recruiting	13
American Ambulance and Oxygen Service	14
Audiology Associates, Inc.	63
The Back Center, Inc.	60
Baltimore Home Health of Maryland, Inc.	201
Blue Cross and Blue Shield of Maryland	90
Boehringer Ingelheim Ltd.	102
Bristol Laboratories	7
A. J. Buck & Son, Inc.	3
Burroughs Wellcome Co.	206
Capital Medical Books	12
Collections, Inc.	202
Comfort Care Medical Equipment	23
Computer Business Systems, Inc.	203
Computerland Towson/Downtown Baltimore	52
Computer System Products	214
Computer Terminal Services, Inc.	216
Contextual Family Center	73
Credit Service International of Baltimore, Inc.	6
Dupont Pharmaceuticals	94
Encyclopaedia Britannica USA	44
Foster/Murray-Baumgartner	208
Glaxo, Inc.	4
Hoechst-Roussel Pharmaceuticals, Inc.	15
E. F. Hutton Consulting Services	51
Kirson Medical Equipment Co.	104
Legg, Mason, Wood, Walker, Inc.	215
Eli Lilly and Company	20
Living Thin/A Lifestyle	34
Management Information Systems Corp.	50
Maryland Army National Guard	106
Maryland Diagnostic Services/Multi-Diagnostic Systems	211
Maryland Medical Laboratory, Inc.	105
Maryland X-Ray Sales & Service	213
May Medical, Inc.	205
Mc Neil Consumer Products Company	74
Mc Neil Pharmaceutical	64
Mead Johnson Nutritional Division	32
Mead Johnson Pharmaceutical Division	81
Medical Group Management Association	204
Med-Chi Agency	53
Medical Mutual Liability Insurance Society of Maryland	70
Merck Sharp & Dohme	209
Merrill, Lynch, Pierce, Fenner, and Smith	62
Metropolitan Surgical Supply	42 & 41
Micro Office Management, Inc.	103
Miles Pharmaceuticals	54
Morgan Financial Group	82
The Neurology Center, P.A.	210
Newtron of Virginia	217
Northern Pharmacy & Medical Equipment	72
Norwich Eaton Pharmaceuticals, Inc.	200
Orem Medical Corporation	75
Ortho Pharmaceutical Corporation	33
Pace Software Services, Inc.	30
Parke-Davis	107
Pfizer Laboratories	11
Pharmatech, Inc.	61
Physicians' Office Computers	101
Poythress Laboratories, Inc.	100
Professional Data Associates	91
Profile Systems, Inc.	92
Prudential-Bache Securities	24
RJL Leasing, Ltd.	83
Reed & Carnrick	35
Reynolds & Reynolds Medical Practice Management Systems	212
A. H. Robins Company	10
Roche Laboratories	85
Sandoz Pharmaceuticals	21
W. B. Saunders Co.	207
Schering Corporation	93
Smith, Abbott & Co., Inc.	55
Smith Kline & French Laboratories	45
E. R. Squibb & Sons, Inc.	95
T. J. Stratton Co., Inc.	80
Stuart Pharmaceuticals/Division of ICI Americas	40
Syn.Op.Sys™	71
Syntex Labs	65
Tasco, Inc.	5
Total Home Nutrition Inc.	84
Towson Surgical Supply	31
U.S. Army Medical Department	108
The Upjohn Company	43
USV Laboratories	2
World Book	22
Wyeth Laboratories	8

Cover Story

Let the Show Begin

James Cox and Sons was awarded the contract to renovate former School #49, which will house Faculty offices. The estimated time for completion is 280 days. The present Faculty building will be upgraded to continue as the prime meeting facility, the library will be expanded, and a new dining room will be located in the basement. Total cost of the renovation is an estimated $2 million, of which $1 million has been raised.

Last October Med-Chi launched a campaign to contact former graduates of the School #49 Accelerated Program to inform them of the renovation of their alma mater. The School #49 project began with a series of radio spots and newspaper advertisements asking for names of students who attended the Accelerated Program. The response was overwhelming, and as a result of the enthusiasm and nostalgia for School #49, a committee of former students was organized to plan a reunion of classes. A history of School #49 has been developed to share with former students, and we will send newsletters periodically to keep them abreast of renovation progress and reunion plans.



The threshold to Med-Chi's new home (J. Jensen).



A weathered School #49 classroom (N. Casey).



Remnants of the building's school days (N. Casey).

Your Medical Faculty at Work

At its meeting on February 7, 1985, the Executive Committee approved the long-range plan of the Public Relations Committee, which included a fiscal consideration of $11,160. The plan includes extensive communication with the print, radio, and television media. There will be some innovations as well as continuation of some past, successful programs. An awards program is being prepared for members of the media to recognize outstanding efforts of various media organizations and individuals who help Med-Chi carry out its objective of informing and educating the public health and medical issues. Meetings among editorial boards and spokesmen for Med-Chi, offering TV spot announcements, developing radio talk shows, and compiling a roster of physician specialists to respond to media inquiries will be implemented.

Discussion with the Deans of the Johns Hopkins University and the University of Maryland Schools of Medicine have been initiated to interest more members of the full-time faculty of those institutions to take an active part in activities of the medical society through membership. Other liaison activities will be instituted.

A Leadership Retreat as approved by Council is being planned in May 1985. Members of the Executive Committee and Delegation to the AMA will meet for a day and a half in a "think tank" situation to discuss current problems and to make some long-range plans for the Faculty.

Nominees for AMA Awards were chosen to be submitted to the AMA in 1985:

Distinguished Service Award—R Adams Cowley MD
Scientific Achievement Award—Arnall Patz MD
Benjamin Rush Award for Citizenship and Community Service—Aris T. Allen MD
Joseph B. Goldberger Award in Clinical Nutrition—Frank L. Iber MD

Suggestions for these awards are solicited for 1986.

There has been a recent notification of the enforcement of an old law requiring proficiency testing of simple labortory procedures in the physicians' office. Because this appears to create a burden on the physician, both financially and in implementation, legal counsel is studying the background and legal implications of this directive so that membership can be advised.

Consideration was given to the establishment of a Conflict of Interest statement to be prepared for officers and other leadership of the Faculty. The Professional Ethics Committee will prepare a statement for submission to the Council.

JOHN SARGEANT
Executive Director

Baltimore County Medical Association

The largest meeting of 1984 was held at St. Joseph Hospital on November 10. The President, John W. Buckley MD called the meeting to order, and thanked Baltasar Velez MD, President of the Medical Staff for the invitation to meet at the hospital. Thomas Allen MD, Program Chairman, introduced Bernard Kleiman MD, Moderator, for the program "Update on Cardiology." Program participants were Drs. John Messina, Robert Brawley, Kenneth Lewis, and Dean Taylor. Following the meeting a reception was held for all attending.

The Annual Meeting of the Association was held in December 1984. Among the guests were: Elliott Fishel MD, President of the Baltimore City Medical Society; Baltasar Velez MD, President, Medical Staff of St. Joseph Hospital; Robert Gibson MD, President, Sheppard Pratt Hospital; Jack Sargeant, Executive Director, Medical & Chirurgical Faculty; and Mrs. Carol Zajano, President, Auxiliary for BCMA.

Michael Gimbel, Drug Abuse Coordinator for Baltimore County, was awarded the Association's Distinguished Service Award for 1984.

The following members were elected by unanimous vote: President-Elect, Thomas E. Allen MD; Vice President, Bernard Kleiman MD; Secretary, Philip Ferris MD; Treasurer, A. H. Ghiladi; and Councilor, B. B. Velez. Delegates to the Medical and Chirurgical Faculty include: Drs. Andrew Alecce, Sheldon Bearman, John Buckley, Esther Edery, Frank Faraino, Gerald Glowacki, A. H. Ghiladi, Charles Hoesch, Christopher Harvey, Paul Koukoulas, John Krager, Herbert Levickas, Louis Pratt, William Reichel, Allen Scott, Margaret Sherrard, John Strahan, and H. Margret Zassenhaus.

Dr. Buckley presented the gavel and symbolic cane to J. David Nagel MD, who presented the Past President's plaque to Dr. Buckley.

A moment of silence honored the memory of George Edwards MD, Hossein Golpira MD, Gunter Schultz MD, Lawrence Post MD, and Alberto Zapata MD.

ALFONSO JANOSKI MD
Editor

The Open Forum

To the Editor:

The January 1985 *Maryland Medical Journal* articles on health education were timely and well done. As a radiologist, I see the unfortunate results of smoking, poor nutrition, lack of exercise, and overall lack of awareness of a person's own responsibility on a daily basis.

I find the association of Med-Chi and the Blues of concern, specifically regarding breast cancer detection. In spite of overwhelming evidence that routine mammographic screening is the most important single aspect of early breast cancer detection, the Blues do not support mammographic screening. This decision can only have been made on purely financial grounds. This policy is inconsistent with the Center for Health Education philosophy as stated on page 56. As noted on page 74, breast cancer is the most common cancer in the female, accounting for 28 percent of all cases in Maryland, and 20 percent of all deaths due to cancer. How in the world can your agency on the one hand promote health education, and at the same time form a joint venture with an association that denies breast mammographic screening?

Programs to promote public awareness of breast cancer are helpful, breast self-examination is helpful, and breast evaluations by physicians during office visits are helpful. However, none of these approaches appears to have made an impact on the early detection of breast cancer, particularly when compared with routine mammography.* Nevertheless, there is probably less than 10 percent compliance with the 1983 American Cancer Society guidelines for periodic mammography, even in those counties that should be the most informed in Maryland, the ones with the highest breast cancer rates, Montgomery, Prince George's, and Baltimore.

The Center for Health Education, Inc. should be a positive force for the people of Maryland, and I applaud your efforts as indicated in the January *Journal*. There is nothing wrong with the Blues participating with a known vested interest in effective health care utilization. However, when their policies, financially based, are in direct conflict with the purpose and goals of the joint venture, you need to evaluate this association more closely.

C.J. TURNER MD
Silver Spring

* Council on Scientific Affairs, "Early Detection of Breast Cancer." *JAMA* 252(1984): 3008–11.

WHAT DO YOU THINK OF THE JOURNAL?
Let us know! Write Open Forum, JOURNAL, 1211 Cathedral St., Balto., MD 21201.

To the Editor:

I've just received my January 1985 copy of the *Maryland Medical Journal* dealing with cancer prevention. While recognizing that lung, colorectal, and breast cancers are numerically the "big three," I'm a little surprised at the virtual absence of comment in any of the articles on the highly effective prevention of squamous carcinoma of the cervix afforded by regular cytologic screening. In properly screened populations, this tumor is virtually unknown. Likewise, it's our common experience that almost the only invasive squamous cancers of the cervix now occur in unscreened women. The two references in your articles, namely, on page 64 and page 68, are tangential to the major issue, to say the least.

I sincerely wish that more emphasis had been given in this otherwise laudable issue to those women who are still dying of cancer of the cervix due to failure on the part, either of the public or medical professionals, to apply existing technology, namely cytologic screening.

RICHARD L. KIRBY, MD
Salisbury

To the Editor:

The Maryland Medical Community is again faced with a proposed "Right to Die Law" to be debated in the current state legislative session. HB 58, proposed by Delegate Dennis McCoy, outlines procedures by which individuals may execute a binding living will. Unlike previous legislative proposals, the current bill imposes grounds for physician discipline in cases in which the physician fails to comply with a valid living will.

Since I am a practicing medical oncologist and have served as Medical Director of a large Hospice organization for over five years, I believe I am qualified to review this proposal. The fact that similar bills have been defeated in Annapolis seven times may indicate how the legislature views such proposals. I support the wisdom of the legislature, and hope they will also find the current proposal to be ill founded, unnecessary, and not in the patient's best interest.

To terminate aggressive treatment or not to resuscitate is an intensely personal decision that develops gradually in a spirit of trust among patient, family, and physician. It requires absolute honesty by the physician and a willingness to be realistic and to look at all the alternatives by the patient and family. It is a decision properly belonging at the bedside or in the home; not in the legislature, law offices, or the courts. Legislation of this sort works against that relationship and places physician and patient in an adversarial relationship.

Delegate McCoy's bill requires certification of terminal illness by two physicians, but the definition of terminal illness is open to very broad interpretation.

> Terminal condition means an incurable condition . . . caused by injury, disease, or illness that, regardless of the application

> of life sustaining procedures and with a reasonable degree of medical certainty, would produce the death of the patient, and to which the application of life sustaining procedures would serve only to postpone the moment of death of the patient.

Since many illnesses meet this definition, the critical question is the immediacy of the patient's potential death. Thus, end-stage heart disease is "terminal" under the law, yet the patient may survive for three to four years or more. Similarly, many patients with major trauma could be denied potentially lifesaving care (albeit with a low chance of success) because they meet the above definition. The bill's failure to define potential survival duration and relative chance for meaningful recovery will undoubtedly lead to numerous questions and legal challenges regarding patient eligibility.

The bill also requires physicians who are unable to comply with the provisions of the living will to transfer the patient to another physician or to be disciplined for their failure to comply. While these provisions would seem to protect the rights of the patient and physician, what if no other physician were willing to accept the patient in transfer or the attending was the only physician in the area with the expertise required by the patient? In these cases, the law would apparently require either that the patient be transferred out of his community with the attendant loss of important local support systems or that the physician to treat the patient in opposition to his own standards of care. Alternatively, the physician could uphold his own ethical standards and run the risk of legal prosecution. Is this humane or compassionate care for the dying? Is this fair to the physician? I don't believe so.

The most glaring deficiency of the proposal (Section 5-605 (C) (4)) is the exemption of paid or volunteer emergency medical providers from the provisions of this act. If we are to enact "Right to Die" legislation, then all providers *must* be constrained and controlled by the law. This exemption would allow ambulance crews to institute any measure dictated by their treatment protocols (including administration of drugs, CPR, and intubation) in complete disregard of the wishes of the patient and family. In a public statement before the Maryland Hospice Network, McCoy stated this section was included at the request of the emergency providers and it was necessary to ensure passage of the legislation. I believe this approach is intolerable.

Emergency providers exist to serve the patient and family. If they perform procedures or other life-sustaining measures in opposition to patient and family wishes, they are hardly "serving" them. What Delegate McCoy really seems to be saying is citizens of Maryland have the right to determine appropriate medical management and to die with grace and dignity except when they are in an ambulance! He obviously feels that a fully trained and licensed physician in Maryland is not competent, willing, or able to deal with the sensitive issue of life-sustaining measures in the dying patient and that the physician's performance must be legislated with the threat of disciplinary action. However, emergency ambulance personnel with little training can continue to follow their protocols and deliver inappropriate care to the dying and will be protected by law. This, because of political expediency. I find this attitude insulting and personally offensive.

The decision to withhold life-prolonging measures is an intensely personal decision that can be decided only by the patient and his or her physician. It is a painful process, both for the patient and the doctor. Nevertheless, if it is to be meaningful, the patient, family, and physician must discuss it and reach a meaningful consensus.

I strongly feel these matters cannot be legislated but must remain an agreement between patient, family, and doctor; an agreement that may change depending on the day-to-day condition of the patient. Furthermore, appropriate palliative care often calls for the use of antibiotics or blood products to alleviate symptoms, yet these important modalities are specifically proscribed by the Living Will Declaration mandated by the legislation. Finally, I am concerned that physicians' real and imagined fears of legal retribution will work against those patients who have not signed a Declaration and will artificially restrict the care delivered to those who have.

The Maryland State Hospice Network represents most Hospices in Maryland. Delegate McCoy appeared before this group in early December 1984 to argue for support of his bill. The Network refused to support the legislation. I urge the Maryland Medical Community to go even further. Not only is this legislation unnecessary, but also it has serious inconsistencies, lacks clarity, and any effectiveness is destroyed by the emergency provider exemption. It will harm those patients Delegate McCoy seeks to protect. I urge you to work actively for its defeat.

P. GREGORY RAUSCH MD
Frederick

To the Editor:

> We of the Maryland State Hospice Network . . . have reviewed each of the proposed bills [HB-58, HB-453, & HB-692], and we feel that the passage of any of them would be desirable. They would all advance the rights of terminal patients while maintaining adequate safeguards for all concerned. However, we strongly feel that HB-692 is the best of the proposed bills.

The preceding is a portion of the testimony given by the Chairman of the Legislation Committee of the Maryland State Hospice Network before the Environmental Matters Committee of the Maryland House of Delegates on 19 February 1985. It is the best summary of our position, a position that is the result of long deliberations, some of which have involved Dr. P. Gregory Rausch.

Hospice is a life-affirming philosophy that seeks to help people "to *live* until they die." All hospice patients have faced their impending deaths and have decided against any extraordinary means to prolong their lives. But we are vitally interested in legislation regarding the

rights of terminal patients to aid both those terminal patients who do not choose hospice care and those people dealing with the patients who have chosen hospice care.

The MSHN has been following legislation regarding the rights of terminal patients for several years, but has not heretofore taken an official stand. Last year, we reviewed both HB-148 and HB-711 and decided neither was adequate enough to merit our support. We obtained a copy of HB-58 in the summer of 1984 and, after reviewing it, thought it was a marked improvement, although notably deficient in certain areas. We then invited Dr. Rausch and Delegate McCoy to participate in a panel discussion of the legislation. Several of Dr. Rausch's concerns expressed then are contained in his preceding letter, and several have been addressed by Delegate McCoy.

Subsequent to this discussion the Legislation Committee met and drafted for the Board of the Network a summary of what we considered the essentials for any terminal rights legislation. This summary was approved unanimously by the Board, and these criteria are those against which we have judged the proposed legislation as well as the model legislation drafted by the National Conference of Commissioners on Uniform State Laws.

We believe it is important to make the following points regarding legislation dealing with the rights of terminal patients:

Legislation protecting the rights of these patients is necessary. The ability of patients to make a binding declaration will allow them to make a positive statement about their preferences as to the manner of their dying. The declaration also will continue these intentions long after the patient has lost the ability to do so. There will be no doubt about the patient's desires.

The declaration can serve as a highly beneficial stimulus to discussion and resolutions among the patient, the physician, and the family. This can serve to facilitate everyone's ability to deal with the approaching inevitable death.

The declaration can serve to protect those abiding by its provisions. Too often medical professionals, paramedical personnel, and families operate out of a fear of criticism or reprisal when making decisions surrounding death. Having the patient's wishes to go by would remove many of these anxieties.

The declaration would allow each individual patient to maintain a degree of self-control over the manner of his or her own death and would obviate many unnecessary and unwanted treatments.

The declaration would serve to identify to care providers the patients who did not wish for extraordinary measures to be employed.

Twenty-three states and the District of Columbia have thought this protection important enough to pass legislation of their own.

Given the basic desirability of legislation to protect the rights of terminal patients, we believe such legislation should have other characteristics, to wit:

The legislation should be binding on health care professionals and paraprofessionals caring for the patient. Any other provision would make the protection a sham. Certainly if a physician cannot provide for his or her patient (in any way), he/she should be honest enough to make the appropriate referral to someone who can.

The legislation should provide adequate means of revocation for the patient who changes his or her mind.

The appointment of an attorney-in-fact would provide additional legal standing to the person making the decisions even if that person is the next of kin.

Terminality is appropriately defined as a condition that, given the current state-of-the-art and science of medicine, will lead to the death of the patient in a short period of time. The identification of when this situation exists is a medical decision that should be left to the attending physician.

The legislation should provide adequate safeguards with regard to matters of euthanasia, pregnancy, and measures of comfort such as food and water.

The existence of a declaration should never be allowed to be the basis for any type of discrimination against the terminal patient.

We have reviewed all the proposed bills, and we believe each is basically sound. However, we would be happy to cooperate in any effort to resolve the problems that we perceive with HB-58 and HB-453, especially those concerning the applicability to emergency medical personnel. Overall, we prefer HB-692. Our reasons also were given in testimony before the Environmental Matters Committee:

> It provides the patient with the desired ability to choose; it fulfills virtually all of the elements which we think important in this type of legislation; it conforms closely to the model legislation proposed by the National Conference of Commissioners on Uniform State Laws; it is the simplest of the three bills; it contains adequate safeguards; and it recognizes declarations appropriately made in other states.

In addition, it will most probably receive reciprocal recognition in other states. Finally, it is our understanding that Dr. Rausch has reviewed this legislation and finds it acceptable.

The Maryland State Hospice Network supports legislation to protect the rights of terminal patients. We would urge your support of the legislation pending before the House of Delegates of the State of Maryland.

CHARLES M. BRIGGS MD
Chairman, Legislation Committee
Maryland State Hospice Network

The Library Page

MARYLAND MED-SIG: A Computer Bulletin Board for Maryland Physicians

On February 1, a remote computer bulletin board became available for all Maryland physicians. The bulletin board, called MARYLAND MED-SIG operates seven days a week, twenty-four hours a day, and is free for members of the medical profession. To use the system, a physician must have a personal computer with a modem that operates at 300/1200 baud. (1200 baud is preferred to reduce on-line time.) Access to the bulletin board is controlled by individual security passwords available to physicians, medical students, researchers, and other authorized users.

The primary purpose of the bulletin board is to facilitate the exchange of information of interest to the medical profession. Physicians will be able to discuss with other physicians the use of computers in their practice and current medical problems. New information about drug reactions will be broadcast on the system as well as announcements about meetings and conferences of medical interest and continuing medical education programs. Physicians will be able to share public domain computer programs over the bulletin board.

The Medical and Chirurgical Faculty will maintain a list of its upcoming meetings on the bulletin board, and, as more physicians join and participate, the Faculty will use it to solicit members' opinions regarding legislative matters and other concerns. The Faculty Library will immediately begin accepting requests for photocopied journal articles and computerized bibliographic searches over the bulletin board. At some future time, it may be possible to send the results of computer searches to physicians via the bulletin board.

The MARYLAND MED-SIG bulletin board was set up through the efforts of H. Gerald Oster MD. Dr. Oster is the chairman of the Faculty's Ad Hoc Committee on Computers in Medicine. The Council recently established this committee to oversee and maintain the bulletin board and to monitor its use by physicians. The Ad Hoc Committee also will monitor other bulletin board and communication systems that might be of interest to physicians, will advise Med-Chi members about computer communication and information systems, and will advise the Council on issues involving the use of computers in a physician's practice. This committee will be Med-Chi's first automated committee and will communicate its meeting announcements and minutes, using the MARYLAND MED-SIG's electronic mail system.

To join MARYLAND MED-SIG a physician should bring his Med-Chi membership card or some other form of medical identification to Computerworld Business Systems (Computer One), Pikesville Plaza Building, 600 Reisterstown Rd., (Reisterstown Rd. and Slade Ave., approximately 1.5 miles south of Beltway exit 20) or to the new Computer One Business Systems in Towson. Computer One has donated space, hardware, and software to operate MARYLAND MED-SIG. The staff will assist physicians with a log on password and access information.

Watch the *Journal* for announcements of further developments in MARYLAND MED-SIG.

JOSEPH E. JENSEN
Librarian

Medical and Chirurgical Faculty of the State of Maryland Library, 1211 Cathedral Street, Baltimore, MD 21201. Joseph E. Jensen, Librarian.

Selected Medical Literature Searches

The following are among the computerized medical literature searches provided to Med-Chi members during January 1985.

	Number of Citations
1. Adolescent suicide	50
2. Adverse effects of nonsteroidal anti-inflammatory drugs on the central nervous system	23
3. Diagnosis of color blindness	20
4. Effects of drugs on memory	48
5. Heart valves and thromboembolism	32
6. Reimbursement mechanisms and quality of health care	21
7. Squamous cell carcinoma and osteomyelitis	27
8. Video display terminals and pregnancy	10
9. Vocal cord paralysis	39
10. Work schedule tolerance, circadian rhythms, and occupational diseases	18

If you would like a copy of one of these searches or a search run on any biomedical topic, call or write the library.

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PREVENTIVE MEDICINE ADMINISTRATION
MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE

201 W. PRESTON STREET/BALTIMORE, MARYLAND 21201/(301) 383-2644

APRIL 1985

SUBOPTIMAL RESPONSE TO HEPATITIS B VACCINE GIVEN BY INJECTION INTO THE BUTTOCK

The antibody response to HB vaccine is higher when vaccine is given in the arm than in the buttock. Furthermore, studies appear to provide an explanation for poor rates of response to HB vaccine reported in some vaccine programs. These data are the first to indicate that response to any inactivated vaccine given intramuscularly to adults may vary with injection site. The Immunization Practices Advisory Committee (ACIP) has previously recommended that the arm is the preferred site of injection for all adult vaccines. However, the present studies demonstrate that the buttock is a commonly used site for HB vaccination. Because of the important implications for use of HB vaccine and other killed vaccines, a prospective study has been initiated to confirm these data.

The physiologic reasons for lower response rate to vaccine injections in the buttock are yet to be defined. The most likely explanation is that injections given in the buttock frequently fail to reach muscle and are instead deposited in fat where the vaccine may not be well mobilized. The authors of a recent study using CAT scans to assess gluteal fat thickness estimated that, when adults are given injections in the buttock using a 3.5-cm (1-3/8-inch) needle, 85% of injections in men and 95% of those in women are deposited in fat rather than muscle. An earlier study showed that lidocaine is mobilized more slowly when injected in the buttock than when given in the arm.

Pending further data, the ACIP and CDC recommend that the arm be used as the site of HB vaccine administration in all adults. For hemodialysis patients, who do not respond as well to vaccine as immunocompetent individuals, vaccine should be given in the arm unless this will jeopardize shunt access. For infants born to HBV-carrier mothers, the preferred site for HB vaccination remains the anterolateral thigh.

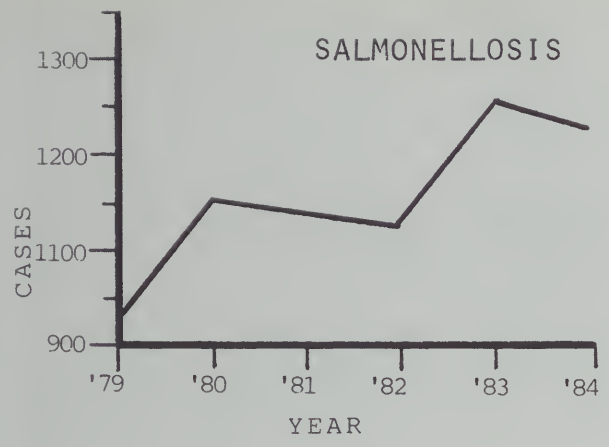
Adapted from the Morbidity and Mortality Weekly Report (MMWR), Centers for Disease Control, March 1, 1985/Vol. 34, No. 8.

REPORTED CASES OF NOTIFIABLE DISEASES IN MARYLAND IN 1984 BY ONSET DATE

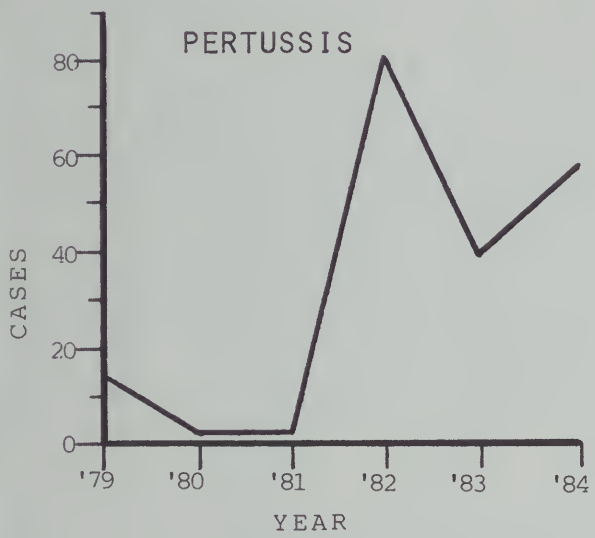
		RUBEOLA (MEASLES)	RUBELLA (GERMAN MEASLES)	INF. PAROTITIS (MUMPS)	PERTUSSIS	VIRAL HEPATITIS A	VIRAL HEPATITIS B	VIRAL HEPATITIS UNSP.	SALMONELLOSIS	TYPHOID FEVER	SHIGELLOSIS	ASEPTIC MENINGITIS	MENINGITIS OTHER**	MENINGOCOCCAL INFECTIONS	VIRAL ENCEPHALITIS	ROCKY MOUNTAIN SPOTTED FEVER	TUBERCULOSIS	MENINGITIS H-FLU	STREPTOCOCCAL INFECTIONS	SYPHILIS, PRIMARY AND SECONDARY	SYPHILIS OTHER	GONORRHEA	ANIMAL BITES
STATE TOTALS	1984	22	1	46	59*	60	694	85	1346	3	242	215	113	46	37	26	427	118	12,868	451	704	28,480	11,484
	1983	11	3	45	39	120	827	95	1407	6	462	273	189	53	24	34	409	93	11,819	517	799	30,368	12,071
	1982	5	36	34	80	177	764	124	1257	12	144	119	162	44	22	37	540	87	12,962	491	803	32,179	11,752
	1981	5	1	109	1	211	768	247	1287	13	182	140	133	66	28	70	621	58	17,882	613	1,044	29,210	11,337
	1980	84	69	339	2	256	597	346	1204	4	190	163	216	55	32	77	610	96	13,847	395	995	27,190	12,962
	Population (ESTIMATE) Maryland State 4,354,200																						
	Baltimore City 742,400	--	--	7	32	9	303	16	450	1	123	52	40	2	5	2	172	31	2,372	277	364	17,178	2,385
	Counties, total 3,611,800	22	1	39	27	51	391	69	896	2	119	163	73	44	32	24	255	87	10,496	174	340	11,302	9,099
POLITICAL SUBDIVISION	Allegany 79,000	--	--	1	--	4	8	2	16	--	1	7	3	--	1	--	4	1	944	2	--	69	334
	Anne Arundel 399,500	1	--	5	--	6	40	5	69	--	7	20	2	2	3	3	20	5	1,330	9	22	870	1,408
	Baltimore Co. 669,200	4	--	9	21	6	47	7	140	--	23	21	9	14	5	5	49	20	570	14	31	1,516	962
	Calvert 41,700	--	--	--	--	--	6	--	7	--	2	--	1	--	1	1	4	1	69	--	1	80	96
	Caroline 24,500	--	--	--	--	1	1	--	16	--	5	3	--	--	--	--	--	--	38	1	7	71	66
	Carroll 109,300	5	--	1	--	1	9	--	60	--	3	2	6	--	3	2	3	3	105	--	3	71	375
	Cecil 63,000	--	--	1	--	1	15	3	17	--	--	5	1	--	--	4	4	1	11	1	6	305	311
	Charles 85,600	--	--	--	--	--	6	4	19	--	1	8	5	2	3	2	7	3	1,233	6	7	250	247
	Dorchester 31,100	--	--	--	3	1	8	--	15	--	4	1	2	--	1	--	6	2	40	1	6	366	87
	Frederick 131,100	--	--	--	2	2	8	--	15	--	--	2	1	1	1	1	3	1	--	1	4	338	309
	Garrett 29,100	--	--	--	--	--	--	2	5	--	--	--	--	--	--	--	1	--	--	--	--	3	112
	Harford 155,600	1	--	3	1	1	16	3	39	--	5	7	5	3	2	--	10	7	118	13	14	335	513
	Howard 143,100	--	--	4	--	1	8	2	56	1	3	15	4	--	1	--	10	3	1,895	3	8	237	626
	Kent 17,000	--	--	--	--	--	--	2	1	--	--	1	--	--	--	--	--	--	12	--	1	27	34
	Montgomery 609,100	11	--	7	--	11	71	16	134	--	30	20	17	10	2	2	58	14	58	15	61	984	1,065
	Prince George's 668,200	--	1	3	--	6	108	11	99	1	26	17	10	5	4	3	49	16	2,341	85	129	4,139	1,607
	Queen Anne's 29,200	--	--	--	--	--	3	1	6	--	1	6	1	--	--	--	1	1	9	1	1	43	90
	Saint Mary's 63,400	--	--	--	--	1	3	--	10	--	--	1	1	2	--	--	2	1	234	--	6	173	219
	Somerset 19,000	--	--	1	--	--	1	--	7	--	1	--	--	--	1	--	2	3	30	1	4	109	56
	Talbot 27,400	--	--	--	--	--	2	--	6	--	--	7	3	1	--	1	1	--	244	1	2	140	43
	Washington 115,000	--	--	1	--	--	16	6	38	--	2	10	--	1	4	--	3	1	424	6	9	243	290
	Wicomico 68,500	--	--	2	--	9	10	2	56	--	3	7	2	2	--	--	16	3	611	7	10	627	181
	Worchester 33,300	--	--	1	--	--	5	3	65	--	2	3	--	1	--	--	2	1	180	7	8	306	68

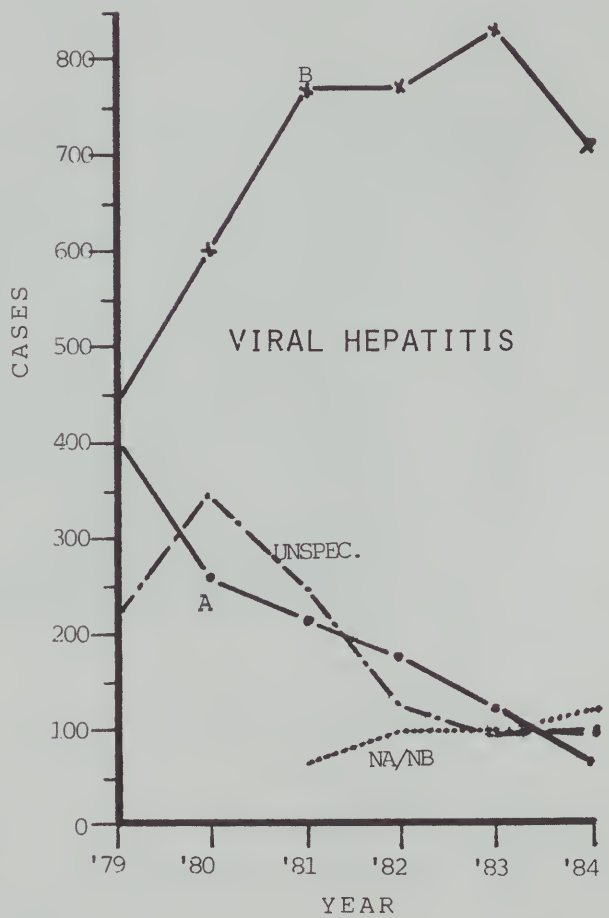
Other Diseases	State	Balto.	Counties
AIDS	67		
Amebiasis	26	14	AA-2, Balto-1, Ce-1, Dor-1, How-4, Mont-2, PG-1
Botulism	1	--	Carroll-1
Chickenpox	2,141	401	Al-4, AA-152, Balto-112, Calv-16, Carol-5, Carroll-9, Ce-1, Ch-30, Dor-5, Fred-24, Gar-1, Har-10, How-575, Mont-6, PG-669, QA-8, StM-5, Som-14, Tal-29, Wash-2, Wic-10, Wor-53
Cholera	1	--	Balto-1
Hepatitis, nA/nB	109	25	Al-1, AA-12, Balto-16, Carol-2, Carroll-1, Ce-3, Ch-3, Dor-1, Fr-2, Har-9, How-4, Mont-6, PG-9, Tal-2, Wash-3, Wic-10
Guillain-Barre' syndrome	18	2	Al-1, AA-1, Balto-2, Har-1, Mont-3, PG-5, Wash-2, Wor-1
Kawasaki syndrome	12	3	Al-1, AA-4, Har-1, How-2, Wic-1
Legionellosis	12	--	AA-3, Carol-1, Fred-1, Har-2, Mont-5
Leprosy	1	--	Mont-1
Malaria	31	4	Balto-3, Carroll-1, Har-1, How-1, Mont-15, PG-6
Poliomyelitis paralytic	1	--	AA-1
Psittacosis	2	--	Balto-1, PG-1
Rabies, animal	1,100	5	Al-3, AA-46, Balto-54, Cal-1, Carol-1, Carroll-148, Ce-1, Ch-7, Fred-247, Gar-23, How-175, Mont-119, PG-239, Wash-30
Non-staph infections in newborn	112	35	Al-3, AA-2, Balto-39, Carol-1, Carroll-5, Fred-1 Har-9, How-1, Mont-6, PG-5, Tal-1, Wash-1, Wic-2, Wor-1
Staph infections in newborn	71	9	Al-2, AA-5, Balto-13, Carol-1, Carroll-1, Ce-7, Ch-1 Fr-1, Gar-1, Har-2, How-10, Mont-6, PG-3, StM-1, Som-2, Tal-1, Wic-5
Tetanus	3	--	AA-1, Mont-1, PG-1
Tularemia	2	--	Balto-1, PG-1

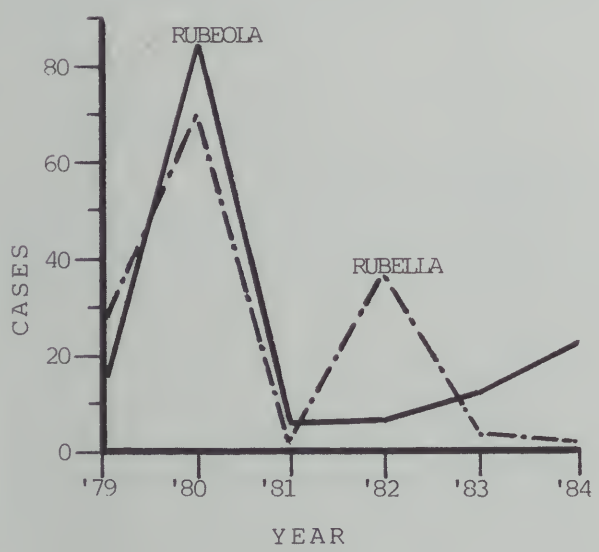
*50 cases were reported through active surveillance set in the Baltimore City and Baltimore County area.
**Excluding H-flu meningitis

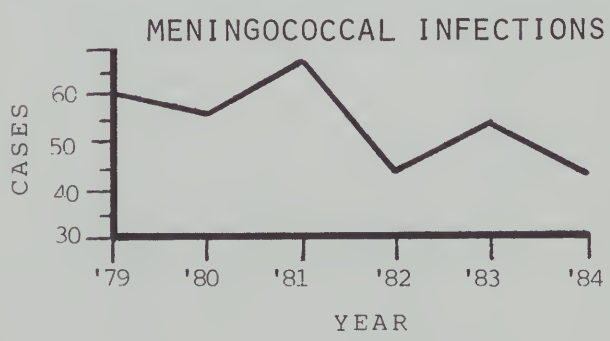

SALMONELLOSIS
1300
1200
1100
900
CASES
'79
'80
'81
'82
'83
'84
YEAR

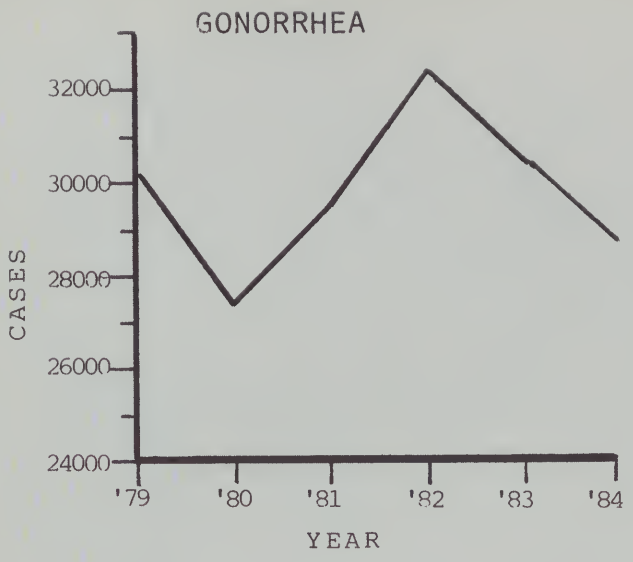

SHIGELLOSIS
600
450
300
150
0
CASES
'79
'80
'81
'82
'83
'84
YEAR

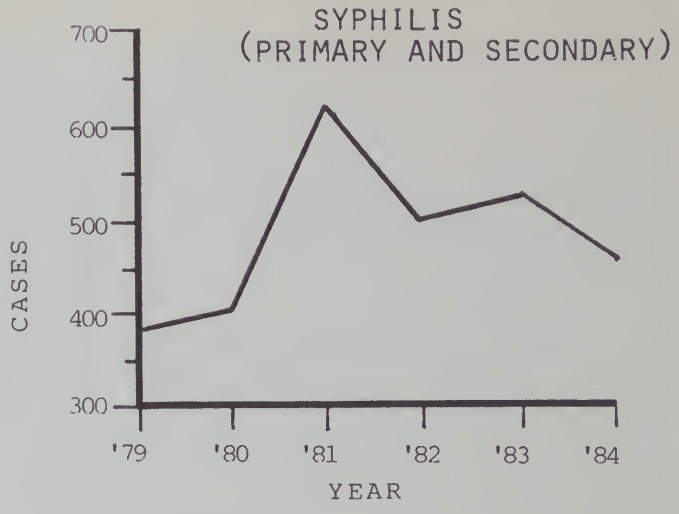

PERTUSSIS
80
60
40
20
0
CASES
'79
'80
'81
'82
'83
'84
YEAR

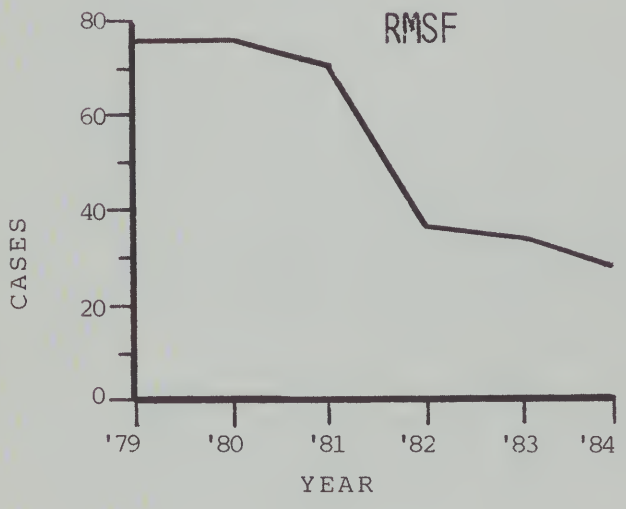

VIRAL HEPATITIS
800
700
600
500
400
300
200
100
0
CASES
B
A
UNSPEC.
NA/NB
'79
'80
'81
'82
'83
'84
YEAR

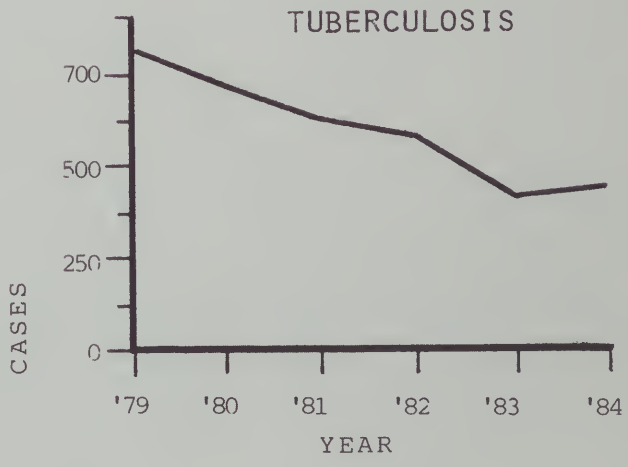

RUBEOLA
RUBELLA
80
60
40
20
0
CASES
'79
'80
'81
'82
'83
'84
YEAR

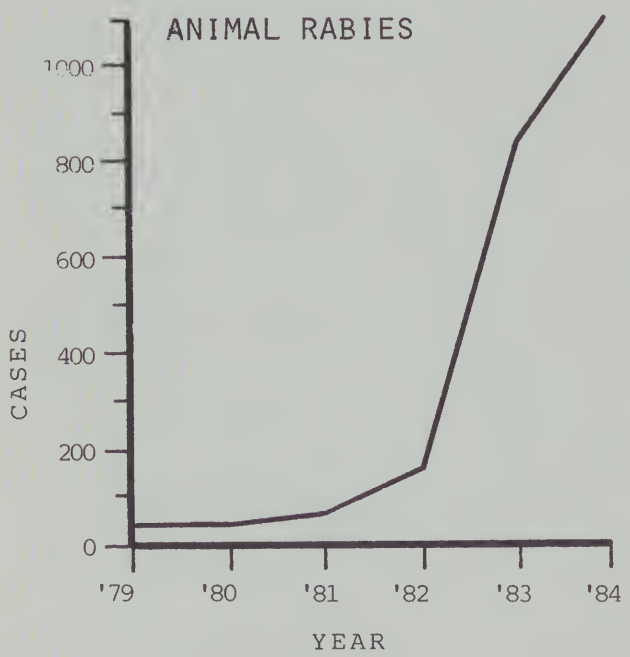

MENINGOCOCCAL INFECTIONS
60
50
40
30
CASES
'79
'80
'81
'82
'83
'84
YEAR

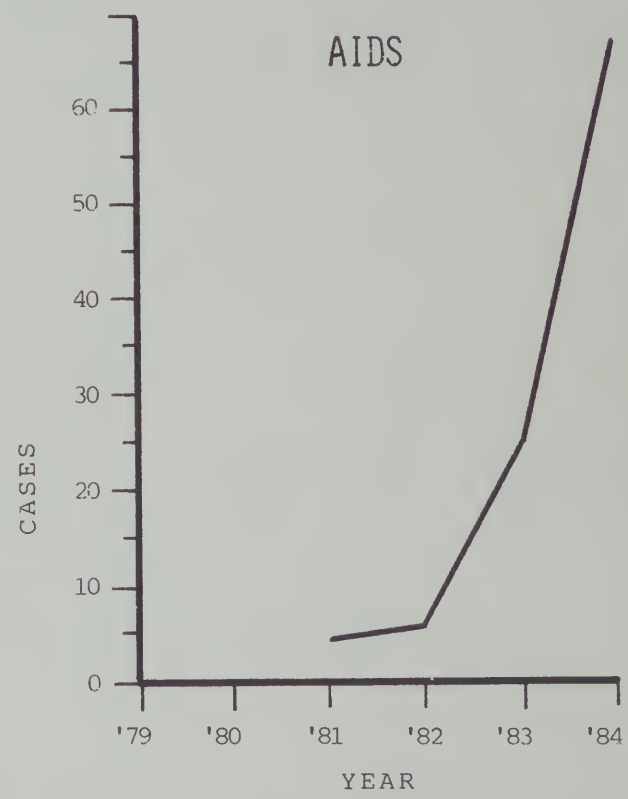

GONORRHEA
32000
30000
28000
26000
24000
CASES
'79
'80
'81
'82
'83
'84
YEAR


SYPHILIS
(PRIMARY AND SECONDARY)
700
600
500
400
300
CASES
'79
'80
'81
'82
'83
'84
YEAR


RMSF
80
60
40
20
0
CASES
'79
'80
'81
'82
'83
'84
YEAR


TUBERCULOSIS
700
500
250
0
CASES
'79
'80
'81
'82
'83
'84
YEAR

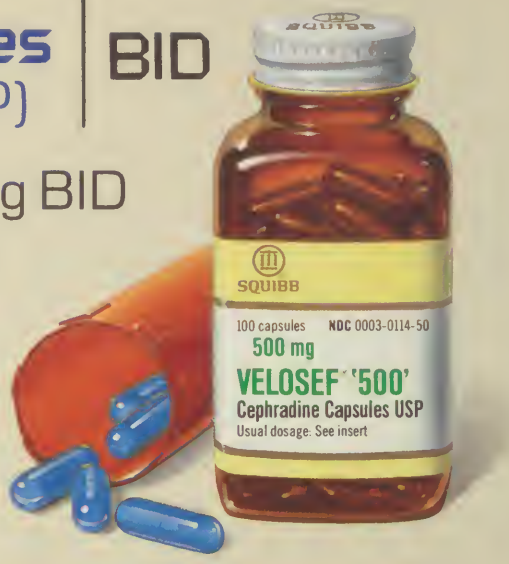

ANIMAL RABIES
1000
800
600
400
200
0
CASES
'79
'80
'81
'82
'83
'84
YEAR


AIDS
60
50
40
30
20
10
0
CASES
'79
'80
'81
'82
'83
'84
YEAR

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INDICATIONS AND USAGE: These preparations are indicated for the treatment of infections caused by susceptible strains of designated microorganisms as follows: Respiratory Tract Infections (e.g., tonsillitis, pharyngitis, and lobar pneumonia) due to *S. pneumoniae* (formerly *D. pneumoniae*) and group A beta-hemolytic streptococci [penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever; Velosef (Cephradine, Squibb) is generally effective in the eradication of streptococci from the nasopharynx; substantial data establishing the efficacy of Velosef in the subsequent prevention of rheumatic fever are not available at present]; Otitis Media due to group A beta-hemolytic streptococci, *H. influenzae,* staphylococci, and *S. pneumoniae*; Skin and Skin Structures Infections due to staphylococci and beta-hemolytic streptococci; Urinary Tract Infections, including prostatitis, due to *E. coli, P. mirabilis, Klebsiella* species, and enterococci (*S. faecalis*).

Note: Culture and susceptibility tests should be initiated prior to and during therapy.

CONTRAINDICATIONS: In patients with known hypersensitivity to the cephalosporin group of antibiotics.

WARNINGS: *Use cephalosporin derivatives with great caution in penicillin-sensitive patients since there is clinical and laboratory evidence of partial cross-allergenicity of the two groups of antibiotics; there are instances of reactions to both drug classes (including anaphylaxis after parenteral use).* In persons who have demonstrated some form of allergy, particularly to drugs, use antibiotics, including cephradine, cautiously and only when absolutely necessary.

Pseudomembranous colitis has been reported with the use of cephalosporins (and other broad spectrum antibiotics); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use. Treatment with broad spectrum antibiotics alters normal flora of the colon and may permit overgrowth of clostridia. Studies indicate a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis. Cholestyramine and colestipol resins have been shown to bind the toxin *in vitro*. Mild cases of colitis may respond to drug discontinuance alone. Manage moderate to severe cases with fluid, electrolyte and protein supplementation as indicated. Oral vancomycin is the treatment of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile* when the colitis is severe or is not relieved by drug discontinuance; consider other causes of colitis.

PRECAUTIONS: General: Follow patients carefully to detect any side effects or unusual manifestations of drug idiosyncrasy. If a hypersensitivity reaction occurs, discontinue the drug and treat the patient with the usual agents, e.g., pressor amines, antihistamines, or corticosteroids. Administer cephradine with caution in the presence of markedly impaired renal function. In patients with known or suspected renal impairment, make careful clinical observation and appropriate laboratory studies prior to and during therapy as cephradine accumulates in the serum and tissues. See package insert for information on treatment of patients with impaired renal function. Prescribe cephradine with caution in individuals with a history of gastrointestinal disease, particularly colitis. Prolonged use of antibiotics may promote the overgrowth of nonsusceptible organisms. Take appropriate measures should superinfection occur during therapy. Indicated surgical procedures should be performed in conjunction with antibiotic therapy.

Information for Patients: Caution diabetic patients that false results may occur with urine glucose tests (see PRECAUTIONS, Drug/Laboratory Test Interactions). Advise the patient to comply with the full course of therapy even if he begins to feel better and to take a missed dose as soon as possible. Tell the patient he may take this medication with food or milk since G.I. upset may be a factor in compliance with the dosage regimen. The patient should report current use of any medicines and should be cautioned not to take other medications unless the physician knows and approves of their use (see PRECAUTIONS, Drug Interactions).

Laboratory Tests: In patients with known or suspected renal impairment, it is advisable to monitor renal function.

Drug Interactions: When administered concurrently, the following drugs may interact with cephalosporins:

Other antibacterial agents — Bacteriostats may interfere with the bactericidal action of cephalosporins in acute infection; other agents, e.g., aminoglycosides, colistin, polymyxins, vancomycin, may increase the possibility of nephrotoxicity.

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Diuretics (potent "loop diuretics," e.g., furosemide and ethacrynic acid) — Enhanced possibility for renal toxicity.

Probenecid — Increased and prolonged blood levels of cephalosporins, resulting in increased risk of nephrotoxicity.

Drug/Laboratory Test Interactions: After treatment with cephradine, a false-positive reaction for glucose in the urine may occur with Benedict's solution, Fehling's solution, or with Clinitest® tablets, but not with enzyme-based tests such as Clinistix® and Tes-Tape®. False-positive Coombs test results may occur in newborns whose mothers received a cephalosporin prior to delivery. Cephalosporins have been reported to cause false-positive reactions in tests for urinary proteins which use sulfosalicylic acid, false elevations of urinary 17-ketosteroid values, and prolonged prothrombin times.

Carcinogenesis, Mutagenesis: Long-term studies in animals have not been performed to evaluate carcinogenic potential or mutagenesis.

Pregnancy Category B: Reproduction studies have been performed in mice and rats at doses up to 4 times the maximum indicated human dose and have revealed no evidence of impaired fertility or harm to the fetus due to cephradine. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, use this drug during pregnancy only if clearly needed.

Nursing Mothers: Since cephradine is excreted in breast milk during lactation, exercise caution when administering cephradine to a nursing woman.

Pediatric Use: Adequate information is unavailable on the efficacy of b.i.d. regimens in children under nine months of age.

ADVERSE REACTIONS: Untoward reactions are limited essentially to G.I. disturbances and, on occasion, to hypersensitivity phenomena. The latter are more likely to occur in persons who have previously demonstrated hypersensitivity and those with a history of allergy, asthma, hay fever, or urticaria.

The following adverse reactions have been reported following use of cephradine: G.I. — Symptoms of pseudomembranous colitis can appear during antibiotic therapy; nausea and vomiting have been reported rarely. Skin and Hypersensitivity Reactions — mild urticaria or skin rash, pruritus, joint pains. Hematologic — mild transient eosinophilia, leukopenia and neutropenia. Liver — transient mild rise of SGOT, SGPT, and total bilirubin with no evidence of hepatocellular damage. Renal — transitory rises in BUN have been observed in some patients treated with cephalosporins; their frequency increases in patients over 50 years old. In adults for whom serum creatinine determinations were performed, the rise in BUN was not accompanied by a rise in serum creatinine. Others — dizziness, tightness in the chest, and candidal vaginitis.

DOSAGE: Adults — For respiratory tract infections (other than lobar pneumonia) and skin and skin structure infections: 250 mg q. 6 h or 500 mg q. 12 h. For lobar pneumonia: 500 mg q. 6 h or 1 g q. 12 h. For uncomplicated urinary tract infections: 500 mg q. 12 h; for more serious UTI, including prostatitis, 500 mg q. 6 h or 1 g q. 12 h. Severe or chronic infections may require larger doses (up to 1 g q. 6 h). For dosage recommendations in patients with impaired renal function, consult package insert.

Children over 9 months of age — 25 to 50 mg/kg/day in equally divided doses q. 6 or 12 h. For otitis media due to *H. influenzae*: 75 to 100 mg/kg/day in equally divided doses q. 6 or 12 h but not to exceed 4 g/day. Dosage for children should not exceed dosage recommended for adults. There are no adequate data available on efficacy of b.i.d. regimens in children under 9 months of age.

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HBP Commentary

Baltimore Awarded a Clinical Center for the Study of Systolic Hypertension in the Elderly

GEORGE ENTWISLE MD and CAROL LEWIS MPH, ScD

Dr. Entwisle is Professor, Department of Epidemiology and Preventive Medicine, University of Maryland School of Medicine, Baltimore, and Dr. Lewis is Executive Director, Maryland High Blood Pressure Commission, 201 W. Preston St., Baltimore, MD 21201.

Maryland physicians are invited to refer their elderly patients with isolated systolic hypertension (ISH) who appear to meet eligibility criteria to the Baltimore Center of the Systolic Hypertension in the Elderly Program (SHEP), a multicenter clinical trial to determine the effects of antihypertensive treatment on morbidity and mortality in patients with ISH.

Isolated systolic hypertension (ISH), defined as systolic pressure ≧160 mm Hg and diastolic pressure <90 mm Hg, is a common condition in the elderly. Population-based data show that the prevalence of ISH rises from approximately 8 percent in persons age 60 to 69 years to approximately 20 percent in persons over age 80.[1] It is estimated that in the U.S. more than three million persons over age 60 have ISH on a single measurement. These persons face an excess risk (two- to threefold) of stroke, other cardiovascular disease, and death. Based on available data, an annual stroke rate of 1.6 percent has been estimated in this population.[2] Moreover, systolic hypertension may play a part in the etiology of multi-infarct dementia. Approximately half the persons meeting the above definition of ISH on a single measurement have sustained ISH, that is, have systolic blood pressure elevation on repeated examinations. The size of this high-risk population is growing; the number of elderly in the United States is expected to increase by 20 percent over the next decade.

No adequate prospective evaluation has been completed to determine the effects of antihypertensive treatment on risks of morbidity and mortality in elderly susjects with ISH. Such treatment might have positive effects similar to those demonstrated for treating diastolic hypertension in middle-aged persons; it also might have adverse consequences. Whether one or the other of these effects predominates can be determined most clearly by carrying out a controlled clinical trial.

The population with sustained ISH is the subject of the Systolic Hypertension in the Elderly Program (SHEP), a multicenter study that will test the efficacy of antihypertensive treatment in these elderly patients. (The pilot study for SHEP has been briefly described in this *Journal*).[3] SHEP is funded by the Division of Heart and Vascular Diseases, National Heart, Lung and Blood Institute, and the National Institute on Aging.

Specific Objectives of SHEP

The primary objective of the study is to determine whether the long-term administration of antihypertensive drug therapy for the treatment of isolated systolic hypertension in elderly persons reduces the incidence of combined fatal and nonfatal stroke. Secondary objectives of SHEP are to evaluate: (1) the effect of long-term antihypertensive therapy on cardiovascular morbidity and mortality in elderly people with ISH; (2) the effect of long-term antihypertensive therapy on other selected morbidity and on mortality from any cause in elderly people with ISH; (3) possible adverse effects of chronic use of antihypertensive drug treatment in this population; (4) the effect of therapy on indices of quality of life; and (5) the natural history of ISH in the placebo population.

The following questions are part of the study:

Biologic effects of reducing systolic blood pressure

1. Will treatment of isolated systolic hypertension (ISH) reduce the combined incidence of fatal and nonfatal stroke (main trial hypothesis)?
   - Will this effect be specific for hemorrhagic and lacunar stroke?
   - Will treatment of ISH prolong survival, given that a stroke has occurred?
   - Will treatment of ISH reduce functional impairment or depression, given survival after a stroke?
   - Will treatment of ISH reduce the incidence of multi-infarct dementia?
2. Will treatment of ISH reduce the incidence of fatal or nonfatal cardiac conditions, that is, myocardial infarction, any cardiac death (including sudden death), or left ventricular failure?
3. Will treatment of ISH reduce the incidence of fatal or nonfatal conditions included in (1) and (2) above plus dissecting aortic aneurysm, renal insufficiency, transient ischemic attack, angina pectoris, symptomatic peripheral vascular disease, or coronary bypass surgery?

Major potential side effects of the drug regimen

1. Will anticipated drug effects occur more often in active than in placebo treated participants (for example, postural hypotension or electrolyte changes)?
2. Will unanticipated drug effects be discovered by comparisons between active and placebo groups?

HBP Commentary is contributed by the Maryland High Blood Pressure Commission. Editors: R. Patterson Russell MD, Past Chairman; Donald O. Fedder PharmBS, DrPH, Chairman; and Carol Lewis MPH, ScD, Executive Director.

Other major indices of net health effects of the treatment program will include all-cause mortality, depression, mental functioning, and incidence of dementia.

Recruitment of Study Cohort

Five thousand men and women nationally who have ISH and are age 60 or over are being recuited; randomized into a double-blind, placebo-controlled, stepped-care treatment program; and followed for an average of five years. The entire study will be carried out by seventeen Clinical Centers; three laboratories for analyzing electrocardiographic, biochemical, and computerized axial tomography (CAT) scan data; and a Coordinating Center.

Recruitment efforts are being carried out at both the national and local level. At the national level endorsements are being sought from major organizations in medicine and aging. A national press release has been developed. At the local level, area physicians, local government agencies, medical societies, and hospitals are being contacted. A set of slides and brochures has been prepared and a logo has been developed for use in presentations to local providers, directors of organizations dealing with the elderly, and potential participants.

The Department of Epidemiology and Preventive Medicine, University of Maryland School of Medicine, has been named a Clinical Center, and it is now recruiting for 300 patients who meet the eligibility requirements for SHEP. Roger Sherwin MD is Principal Investigator, and George Entwisle MD and Elijah Saunders MD are Co-Principal Investigators. Please call Dr. Entwisle (528-6077) to discuss details of the study, the possible eligibility of your patient(s), and what collaborative efforts are involved. The Baltimore investigators also will be pleased to attend professional meetings to make presentations about SHEP.

Eligibility

Patients must be 60 years old or older to be considered for participation in the study. Patients 60 or older who have systolic blood pressures $\geqq$150 mm Hg and diastolic blood pressures <90 mm Hg (without medication) will be evaluated. For persons who meet these criteria, there are other causes for exclusion:

- an anticipated change of residence of more than 50 miles in the next year
- a cardiac pacemaker in use
- myocardial infarction or coronary artery bypass surgery in the past six months
- treatment with anticoagulants or insulin
- stroke with residual effects

After two baseline visits, approximately 300 participants will be randomized at the Baltimore Center to either medication or matching placebo in a double-blind manner. The objective of the treatment program is to use the minimal amount of medication that will keep systolic blood pressure at or below goal.

Standardized general information on nutrition, smoking, and exercise will be given to all participants. Moderation of salt intake in favor of foods high in potassium will be recommended. Avoidance or reduction of obesity and regular gradual exercise will be advised.

Follow-up Procedures

All participants are required to be seen in the clinic at one month, two months, and quarterly after the date of randomization. All required visits will include measurement of blood pressure, heart rate, and weight, and a general interval history including screening questions for stroke and other endpoints and the use of concomitant medications.

An annual visit will include all procedures in the one-month, two-month, and quarterly visits, plus a more comprehensive history and physical examination, complete side-effect questionnaire for all participants, a brief neurologic exam, and a behavioral evaluation. Blood chemistries, urinalysis, hematology, and a 12-lead resting ECG and two-minute rhythm strip will be included at annual visits.

Other visits may be scheduled at the SHEP clinic for various reasons.

Importance of the Study of Isolated Systolic Hypertension

Isolated systolic hypertension brings considerable risk to the elderly, in terms of stroke and other cardiovascular disease, yet there is no definitive information about the beneficial or negative value of treating ISH with known antihypertensive agents. Well-known clinical trials have shown marked benefit from treating first severe, then moderate, and finally "mild" diastolic hypertension. No comparable trials exist for ISH, which (compared to diastolic hypertension) is relatively rare except in persons over 80. For this landmark study to be successful, 300 persons in the Baltimore area must meet all eligibility standards and agree to participate over five years. *Every case is valuable.* Area physicians who refer patients will contribute to knowledge about the efficacy of treatment not only for their patients but also for all elderly persons with ISH. They will, of course, remain as the primary medical providers for their patients through collaboration with the study physicians at the University of Maryland School of Medicine. Physicians will be kept informed of the progress of their patients in the trial and will be consulted as necessary on decisions affecting their care.

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Maryland Oncology Newsletter

Management of Primary Adenocarcinoma of the Large Bowel

Surgery plays a major role in the management of large bowel cancer. There are three types of surgery: prophylactic, curative, and palliative.

Prophylactic surgery, for example, colectomy in patients with high-risk factors (such as persistent ulcerative colitis and multiple or familial polyposis), may prevent cancer from developing in those patients.

Curative surgery is the single most effective and proved method in the management of adenocarcinoma of the colon and rectum. The purpose of such an approach is resection of the primary tumor and the draining of regional lymph nodes. This is because we cannot determine during surgery whether these lymph nodes contain metastasis. To remove the nodes, which lie adjacent to the blood vessels in the mesentery of that area of the bowel, the blood vessels have to be excised from their origin, removing the mesentery of the region. This will result in sacrificing some bowel that is supplied or drained by these vessels. Therefore, the surgery must be defined as right or left hemicolectomy, extended sigmoid resection, and abdominoperineal resections. Such an approach gives the best survival, regardless of the "No Touch" technique.

While the major complication after colon surgery is anastomotic leaks, we have found that anal sphincter dilatation at the end of the operative procedure prevents, to a large extent such complication. The use of the EEA stapler for low anterior anastomosis has a great advantage of carrying very low anastomosis in a short period of time. However, a standard cancer surgery, removing the surrounding rectal tissues containing the lymph nodes, must be performed to avoid local recurrences, which have a fatal outcome.

Any tumor that can be felt by a digital rectal exam necessitates abdominoperineal resection. If distant metastasis is noted during surgery, it must be biopsied for histological confirmation because some benign lesions may look like metastases. Furthermore, if a single small metastasis is noted, it should be excised with free margins. On the other hand, if a large metastasis is discovered, it should be biopsied and the area investigated for future resectability.

Adjuvant therapy is initiation of radiation therapy, chemotherapy, or immunotherapy *within four weeks of curative surgery*, in hope of prolonging the disease-free survival in patients with high risk of developing metastases, such as in patients with Dukes B and C carcinoma. While post-operative radiation therapy is being investigated after abdominoperineal resection for adenocarcinoma of the rectum and seems to be promising, it cannot be applied to the colon.

On the other hand, adjuvant systemic chemotherapy with a single agent (5-FU), two drugs (5-FU + Methyl-CCNU), or three drugs (5-FU + Methyl-CCNU + Vincristine), as well as adjuvant nonspecific immunotherapy by BCG or C. Parvum have not been beneficial in patients with adenocarcinoma of the colon or rectum. However, we have been employing three different approaches: (A) Banked associated antigen as tumor-specific immunotherapy for patients referred to us within four weeks of their primary curative surgery elsewhere. (B) Tumor cell immunotherapy prepared from the patient's own tumor if surgery is performed at our institute. (C) Patients who undergo definitive surgery at our institute are offered portal vein cannulation at the time of surgery for one week of 5-FU infusion in the immediate postoperative course. This is to test the Taylor approach, which claims low incidence of liver metastases.

All of the patients must be followed every three months for three years, then every six months thereafter.

If you have questions, call or write the Surgical Oncology Program, University of Maryland Medical System, Room N13E02, Baltimore, MD 21201 (301-528-5224).

E. GEORGE ELIAS MD
University of Maryland, Surgical Oncology Program

Consultation

The Faculty's radio program on WBJC-FM (91.5 mHz on your dial) is on the air between 10 and 11 a.m. on alternate Wednesdays

May 1	**Homosexuality**	Kenneth Solomon MD
May 15	**Chemical Dependency and Addictions**	Franklin Evans MD
May 29	**Sexually Transmitted Diseases**	Edward Sawada MD Edward Campbell MD
June 12	**Anesthesia—To Sleep, to Dream**	Charles Hobelmann MD
June 26	**Ears, Noses, and Throats**	Michael Holliday MD

One Minute With Diabetes

Doctor, despite carefully following my 1,800 calorie ADA Meal Plan and taking Humulin N 21 units plus Humulin R 6 units before breakfast (7:30 A.M.) and 12 units Humulin N plus 6 units Humulin R before supper (5:00 P.M.) I persistently have glucosuria in the double-void specimen. The remainder of my tests before meals and at bedtime are always negative for glucose. I am afraid to increase the P.M. dose for fear of a night reaction. My last two glycohemoglobin tests have been 5.8% and 7.1% (normal 3.4–6%). Self blood glucose monitoring is less than 130 mg./dl. at all times except in the mornings and sometimes even that is normal. What can I do to correct the problem of morning glycosuria?

This very active 70-year-old man was advised to try taking his evening dose of insulin about 7:00 P.M. (after the evening meal) instead of 5:00 P.M. and to telephone his test results after a week of trial with that program. When he telephoned his progress, he reported no further glycosuria and no hypoglycemic reactions.

A point to remember is that the newer, more purified insulins have a shorter duration of action than the older beef-pork insulins. This is because the antibodies to beef-pork species produced in the body slow the duration of action of insulin. Apparently in this man Humulin N produced less antibodies, and the NPH insulin had a shortened duration of action. It did not adequately control his blood glucose for more than twelve hours.

It would be worth a trial, where morning hyperglycemia or glycosuria occurs persistently, to give the evening insulin dose after dinner or even as late as bedtime, depending on the meal pattern and time of going to bed.

DeWITT E. DeLAWTER MD
Editor

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Occult Hemorrhage in a Neonate with Hemophilia A

FRED J. HELDRICH MD and PRADEEP P. GARG MB

Intracranial hemorrhage in neonates is a problem of major clinical importance and a significant cause of mortality and morbidity. While it occurs most frequently in preterm, low-birth-weight infants, it is being recognized with increasing frequency in term newborns.[1–8] Although trauma and hypoxia are considered the major causes of intracranial hemorrhage in full-term newborns, coagulation defects also are recognized etiologies. Included in potential coagulation defects is the heritable sex-linked disease hemophilia A.[9–12]

Dr. Heldrich is Chairman, Department of Pediatrics, St. Agnes Hospital. Dr. Garg is also with the Department of Pediatrics, St. Agnes Hospital. Correspondence: Dr. Heldrich, Department of Pediatrics, St. Agnes Hospital, 900 Caton Ave., Baltimore, MD 21229.

A 6-day-old male infant was admitted because of jaundice, lethargy, and a full anterior fontanelle. He had been delivered vaginally with low forceps after a normal gestation and labor. Weight 3405 gm. Head circumference 34 cm. No caput or cephalohematomas were seen. Apgars were 9 at one minute and 9 at five minutes.

Because the patient's 3-year-old brother is a hemophiliac (Factor VIII deficiency), a Factor VIII level was done on the second day of life and was 2.5 percent. Circumcision was not performed. His immediate neonatal course was uneventful, and he was discharged on the third day of life, taking breast feedings well.

The day prior to admission, he seemed less active and nursed poorly. When seen by his primary care physician on the sixth day of life, he was noted to be lethargic and jaundiced and had a full anterior fontanelle. There was no history of trauma.

On admission, weight was 3.37 kg. Head circumference 36.0 cm. Temperature 37.4° Centigrade. Pulse 158/minute. Respirations 32/minute. He was lethargic, responded to stimulation with a weak cry, and had a tense, bulging anterior fontanelle. There was no visible evidence of trauma. Generalized icterus was noted. On examination, no focus of infection could be found. Blood and urine specimens were obtained for culture. Blood type was A, Rh positive. Coombs test negative. Serum sodium 148 mEq/L, chloride 109 mEq/L, potassium 5.1 mEq/L, CO_2 29 mEq/L. Blood urea nitrogen 9 mg/dl, glucose 102 mg/dl. Urinalysis negative. Hemoglobin 17.1 gm percent. Hematocrit 52.5 percent. White blood count 23,100/cu mm with 67 percent segmented neutrophils, 8 percent bands, 23 percent lymphocytes, 2 percent monocytes. Total serum bilirubin 10.2 mg/dl; 9.1 mg/dl nonconjugated. After giving cryoprecipitate to raise his Factor VIII level to a calculated 100 percent, lumbar puncture was performed. The cerebrospinal fluid was bloody, indicating blood in the subarachnoid space. Antigen for group B Streptococcus was not present in urine. All cultures were negative.

Antibiotics were begun intravenously, pending results of the cultures. A sonogram (real time B-mode ultrasound) disclosed dilated lateral and third ventricles but no bleed (Figure 1). Ventricular dilatation was confirmed by computerized axial tomography, which further identified subdural hemorrhage with layering

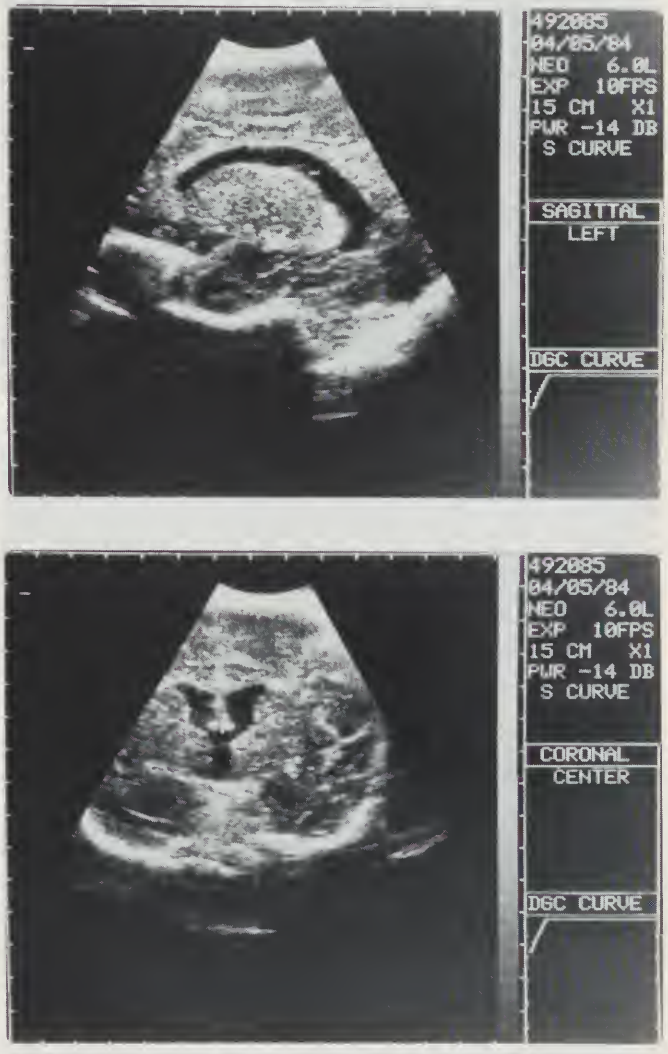


Figure 1: Sonogram, saggital view, demonstrating dilatation of the left lateral ventricle (A). Coronal view showing enlargement of both lateral and third ventricles (B).

over the tentorium, more pronounced on the left than on the right (Figure 2, next page).

Therapy continued with cryoprecipitate daily, sufficient to provide a Factor VIII level of 50 percent just prior to each dose, for ten days. Clinical improvement occurred with an increase of overall activity and responsiveness, good feeding, progressive reduction in jaundice, and weight gain. Before discharge on the twelfth hospital day, head circumference was 36.5 cm, 0.5 cm larger than on admission, and a repeat sonogram

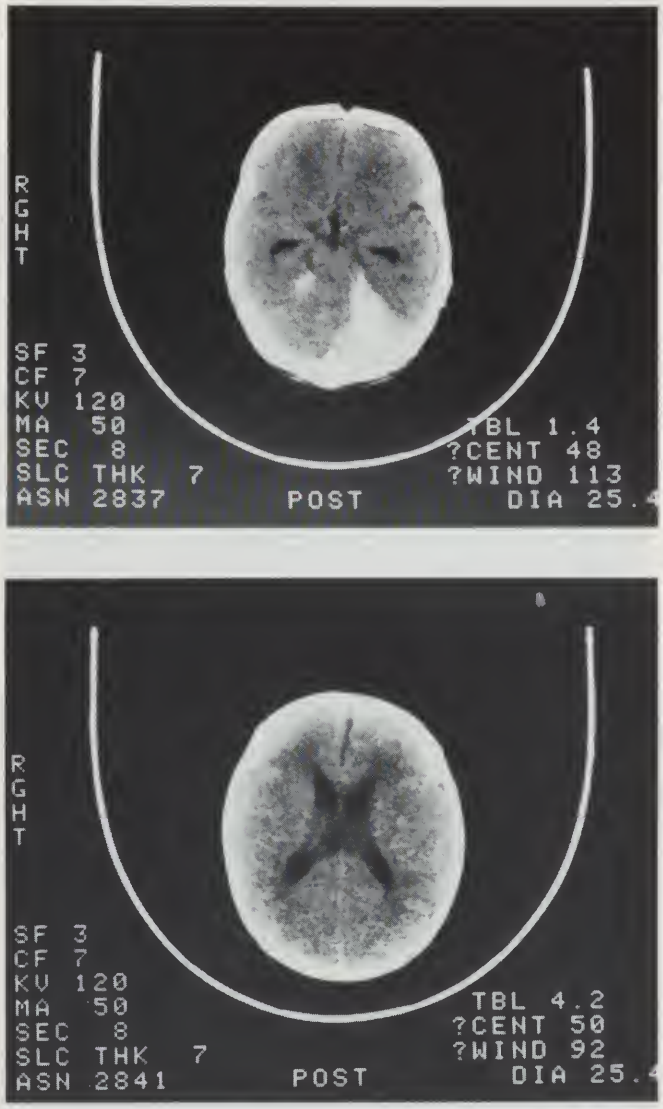


Figure 2: Computed tomogram demonstrating layering of subdural blood along the tentorial surfaces, more marked on the left (A). Dilatation of the lateral ventricles is demonstrated in the coronal view (B).

revealed no increase in ventricular dilatation. One month later, head circumference was 41.5 cm, the infant was doing well, and a sonograph revealed resolution of ventricular dilatation (Figure 3, next page).

Discussion

Intracranial hemorrhage as a complication of hemophilia occurs most frequently in young children, usually as a result of trauma.[13–18] Since the deficiency of Factor VIII activity in hemophilia exists from birth, it is surprising that few neonates with deficient Factor VIII activity have been reported to have intracranial bleeding as a result of the trauma of delivery.[19–21] The major source of bleeding in neonates with hemophilia has been circumcision; however, intracranial hemorrhage remains the most serious potential complication.[22–26]

Symptoms of intracranial bleeding vary depending on the magnitude of the bleed and its location. These symptoms direct attention to the central nervous system: seizures, sudden occurrence of apnea and/or bradycardia, flaccidity, hypotonia, and a tense fontanelle.[27–29]

At times, symptoms may be less dramatic. Symptoms were not apparent in our patient until the fifth day of life. Decreased activity and poor nursing were the earliest symptoms; jaundice and a tense anterior fontanelle were not noted until six days of age. Since these symptoms are compatible with sepsis, antibiotic therapy was begun after obtaining appropriate cultures. The patient's Factor VIII level was in the moderate severity range (2.5 percent); thus, a diagnostic lumbar puncture as part of the evaluation for infection was not performed until cryoprecipitate had been infused to raise the Factor VIII level to a calculated 100 percent. Bloody cerebrospinal fluid was obtained and indicated subarachnoid bleeding.

Studies have shown that real time B-mode ultrasound and computerized axial tomography may fail to detect intracranial bleeding because of the size, location, or age of the bleed. Used together, these modalities complement each other and improve diagnostic capabilities.[30–31] An initial sonogram had failed to identify the intracranial bleed, but did disclose dilatation of both lateral and third ventricles (Figure 1). The CT scan revealed subdural hemorrhage layered over the tentorium, more marked on the left than on the right, in addition to ventricular dilatation. There was no evidence of intraventricular or intracerebral hemorrhage (Figure 2).

Using croyprecipitate to maintain a Factor VIII level above 50 percent over a ten-day period, there was progressive clinical improvement. A repeat sonogram at six weeks of age demonstrated the lateral and third

ventricles had returned to normal size (Figure 3); thus, a repeat CT scan was not deemed necessary.

Intracranial hemorrhage secondary to hemostatic failure often leads to subarachnoid bleeding over the temporal and occipital lobes as well as cerebellar hemorrhage. Subdural, subarachnoid, and intracerebral sites have been reported locations of intracranial bleeding in patients with hemophilia, and trauma is frequently an associated factor.[32-38] Trauma, as evidenced by difficulty during labor or delivery, was lacking in our patient. A traumatic event may have occurred after delivery, but both history and lack of objective findings (such as scalp ecchymoses or hematomas) fail to support this possibility. Intervals as long as nine days between the traumatic event and development of symptoms secondary to intracranial hemorrhage have been documented in patients with hemophilia; thus, the trauma of a "normal" vaginal delivery may have been the initiating factor.[39-41]

Infants with hemophilia are not always identified at birth. There is the distinct possibility of a negative family history even if the factor deficiency is severe.[42] While bleeding from circumcision is the most common method of presentation in neonates unsuspected of having hemophilia, the majority of those circumcised do not bleed excessively.[43,44] Release of tissue thromboplastin secondary to the crush injury of the circumcision will effectively initiate the clotting mechanism.[45] This patient's brother was circumcised uneventfully; his factor deficiency was not identified until he presented with a significant mucous membrane bleed at six months of age. A thorough family history revealed the presence of Factor VIII deficiency in a cousin.

Because our patient had a positive family history of hemophilia, a Factor VIII level was obtained. If he had been the first sibling, the urgent need to perform a lumbar puncture (to verify the diagnosis of meningitis) might have resulted in failure to elicit the positive family history. This case emphasizes the importance of inquiring about bleeding disorders in family members prior to performing any procedure likely to be complicated by bleeding. In addition to circumcision, procedures that may lead to bleeding include lumbar puncture and suprapubic bladder aspiration.

With the use of cryoprecipitate and factor concentrates, the management of hemophilia has been improved significantly, and diagnostic procedures can be performed with reasonable safety.[46-48] In a patient with hemophilia, using cryoprecipitate before performing the lumbar puncture should protect against a hemorrhagic complication. When the cerebrospinal fluid is bloody, computerized axial tomography may confirm the presence, location, and extent of an intracranial bleed. Therapy with cryoprecipitate and/or factor concentrate

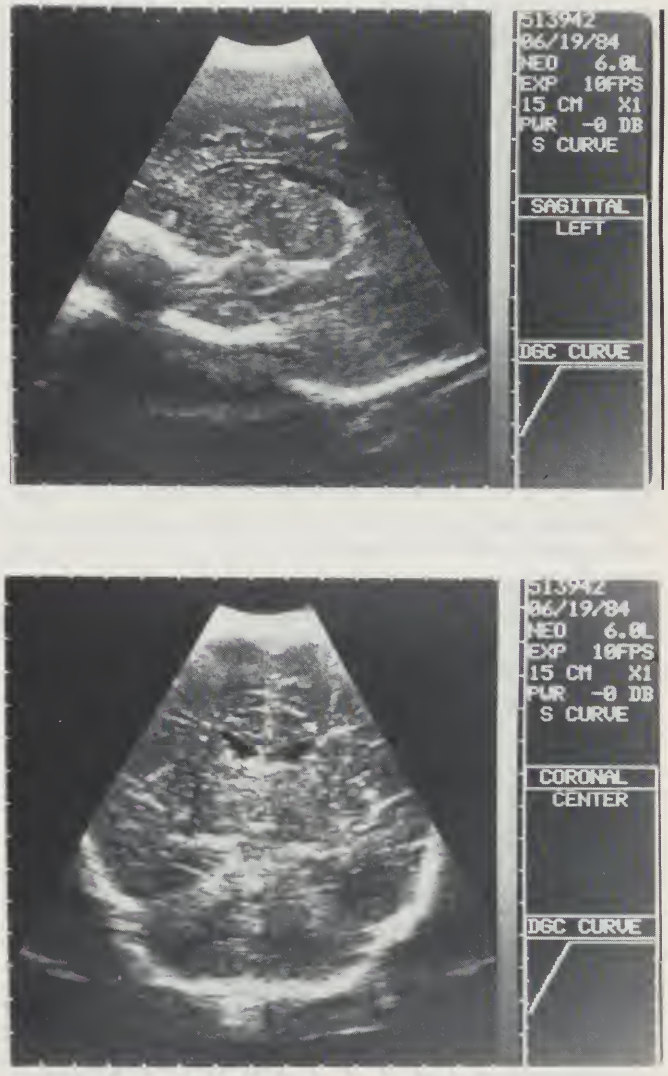


Figure 3: Marked resolution of ventricular dilatation, 6 weeks after therapy, is demonstrated by sonography in the saggital view (A) and coronal view (B).

has reduced the mortality and morbidity of intracranial hemorrhage in patients with hemophilia.[49–53] When continued at a dose sufficient to maintain a Factor VIII level of at least 50 percent (as demonstrated in our patient), cryoprecipitate may be an effective means of preventing further bleeding.

Ultrasound provides a safe, noninvasive method for diagnosing ventricular dilatation and for following changes in ventricular size in patients who have demonstrated this complication. Patients who may require ventricular shunts can be identified by this procedure. Computerized axial tomography may be repeated to detect extension of hemorrhage or documentation of secondary abnormalities.

Acknowledgment

The authors thank Dr. Lyle Saylor who interpreted the sonograms and computerized axial tomography.

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Endoscopic Sclerotherapy of Esophageal Varices

DAVID B. DOMAN MD

Endoscopic injection sclerotherapy is a useful therapeutic modality in controlling acute variceal hemorrhage and in the prevention of recurrent bleeding episodes. Recent data clearly have demonstrated the safety of sclerotherapy as refinement of techniques and equipment has evolved. Extended follow-up will determine long-term survival, effects of technique modification, and benefits of prophylactic treatment.

Dr. Doman is an Assistant Clinical Professor of Medicine at George Washington University School of Medicine and is in private practice in Wheaton, MD.

The treatment of patients with bleeding esophageal varices historically has been one of great frustration. Traditional therapeutic modalities such as pitressin infusion[1] or the Sengstaken-Blakemore tube,[2] though effective in controlling the acute episodes, do not reduce the risk of subsequent long-term hemorrhage. Portacaval shunt surgery was developed in response to this need; unfortunately, the reported[3] 80 percent mortality in the acute setting and the increased risk of subsequent encephalopathy have limited the role of operative intervention. Prophylactic shunt surgery (that is, in nonbleeding patients) has fallen by the wayside in view of data demonstrating the lack of change in long-term survival.[4] Data on the "Warren shunt" have demonstrated a benefit in this regard;[5] however, the technical expertise and the time required for this selective shunt obviate it as an option in the treatment of acute esophageal variceal bleeding. Newer therapeutic techniques for bleeding esophageal varices, such as percutaneous transhepatic portovenous embolization[6] and beta blockers,[7] appear to have a limited role. The use of endoscopic heater probe coagulation or laser therapy (in a large series) has not been demonstrated to be efficacious, safe, or cost effective. Gastroesophageal stapling[8] has met with limited enthusiasm.

Sclerotherapy

Sclerotherapy was described first in 1939.[9] It is an adaptation of a long-standing therapy to treat varicose veins. Early attempts at endoscopic sclerotherapy failed to achieve popularity due to the limitations of rigid esophagoscopy. With the technical advances in flexible fiberoptic endoscopy, sclerotherapy has become a viable therapeutic option.

An exciting recent innovation in therapeutic gastrointestinal endoscopy is sclerotherapy of esophageal varices. This technique entails the injection of a sclerosing agent into varices under direct endoscopic visualization. When injected intravariceally or paravariceally, the sclerosing agent can provoke a localized inflammatory reaction. This reaction can lead to subsequent thrombus formation and eventual obliteration of the variceal lumen (Figure 1). Numerous large-scale international prospective studies[10,11] have demonstrated a role for endoscopic sclerotherapy in the control of acute variceal hemorrhage. In 90 to 95 percent of post-sclerotherapy patients the varices were obliterated completely, and risk of subsequent bleeding was eliminated. Preliminary long-term survival data are very encouraging.[12,13]

Technique

In the acute setting of variceal hemorrhage, bleeding can be controlled with a combination of intravenous pitressin, Sengstaken-Blakemore tube, and/or sclerotherapy. Once bleeding has been controlled, more definitive therapy to obliterate the varices can be achieved with sequential sclerotherapy treatments. This technique usually involves a series of circumferential injections beginning at the gastroesophageal junction, with subsequent extension proximally (Figures 2 and 3, next page). During one sclerotherapy session 10 to 20 injections (involving 10 to 20 cc of sclerosing agent) are performed 1 cm apart. A common sclerotherapy sequence involves treatments at the first hospital day and then seven days thereafter. If more treatments are required they can be repeated at monthly intervals. A typical patient requires two to three treatments to achieve complete obliteration of the varices.

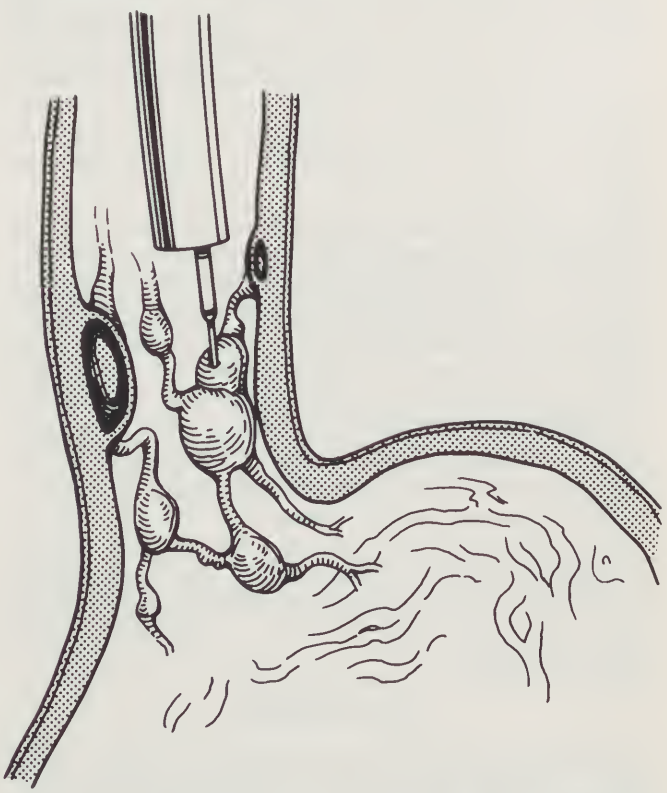


Figure 1. Site of injection sclerotherapy. (The author thanks Robert Sanowski MD for this illustration.)

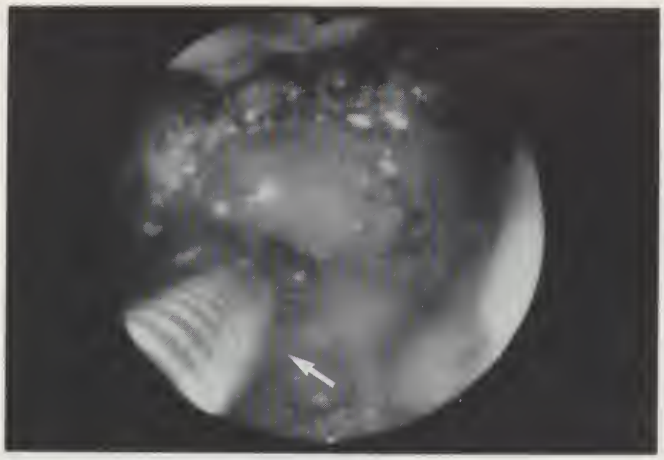


Figure 2. Endoscopic sclerotherapy in progress: marker indicates injection catheter.



Figure 3. One week post-sclerotherapy: marker indicates thrombosed injection site.

Advantages/Side Effects

The advantages of sclerotherapy are many. It requires only light sedation (routine endoscopic sedation with Valium, Demerol, etc.). Sclerotherapy can be performed in the endoscopy suite, intensive care unit, or emergency room using a basic upper GI endoscope, sclerotherapy injection needle, and sclerosing agent such as sodium tetradecyl or sodium morrhuate. Only 15 to 30 minutes are needed for each sclerotherapy session.

Recent data have demonstrated clearly the safety of sclerotherapy as the refinements of techniques and equipment have evolved.[14,15] Side effects are few. A chemical-mediated febrile response analogous to that of cancer chemotherapy may cause a transient low-grade fever (under 100°F) in 20 percent of sclerotherapy patients. Transient dysphasia also can occur secondary to the variceal edema. Small ulcerations can occur at the injection site and usually will heal (without therapy) in several days. Serious complications such as bleeding, esophageal perforation, mediastinitis, shock lung, and stricture occur in only 1 percent of sclerotherapy patients.

The Child-Turcotte classification[16] historically has been used to characterize patients with portal hypertension and in turn their candidacy for shunt surgery. Clearly, patients with less debility (for example, Child's class A) are better candidates for shunt surgery than those with advanced disease (Child's class C). An advantage of sclerotherapy is that it may be done regardless of the Child's class. Furthermore, a recent review[17] of the Cleveland Clinic Experience has indicated that the best survival indicator after sclerotherapy is successful obliteration of the varices.

Controlled trials demonstrating safety and efficacy of sclerotherapy in the treatment of gastric varices are in progress; most authorities currently advocate shunting procedures for patients with recurrent gastric variceal hemorrhage.

Conclusion

Endoscopic sclerotherapy should be viewed as a palliative therapeutic maneuver. Although effective in obliterating esophageal varices, sclerotherapy does not alter the underlying portal hypertension. Such patients are therefore at risk for hepatic encephalopathy and possible recurrence of varices. Should varices recur, repeat sclerotherapy or elective shunt surgery should be considered.

Many questions remain to be answered about sclerotherapy: optimum number of treatments, cost-effectiveness of prophylactic sclerotherapy (that is, in patients with varices that have never bled), best injection technique (intravariceally vs. paravariceally), and long-term survival rates.

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Editorial

Esophageal Varices

Hemorrhage from esophageal varices remains a clinical problem without a good solution. Mortality is high (up to 50 percent in reported series)[1] and no therapeutic intervention has been shown to be of clear benefit. Surgery to decompress the portal system has advocates[2] but has not been beneficial in controlled trials.[3] Therapy with Inderal has been shown to reduce portal pressure (the underlying facilitator of bleeding), but clinical effects on bleeding have been mixed,[4,5] and beta blockade has a deleterious effect if bleeding does start.

Sclerosis of esophageal varices, as advocated by Dr. Doman in the preceding article, is a method of therapy currently undergoing intensive evaluation. Sclerotherapy might be used as prophylactic therapy for patients who never have bled, as therapeutic treatment for patients who have bled previously, or for patients with acute bleeding.

Patients with varices who never have bled have a comparatively favorable prognosis and generally are not considered candidates for intervention. Patients who have bled but currently are not bleeding are the primary group for whom sclerotherapy should be considered. Treatment usually requires four to six endoscopic sessions and clearly reduces the rate of bleeding.[6,7] The effects on mortality are uncertain.[8,9] There is no agreement about type of sclerosant or method of injection (intravariceal or paravariceal), and further investigation is under way.

Sclerotherapy for acutely bleeding varices is a major undertaking because visualization is difficult. Active resuscitation of the patient and often endotracheal intubation are required. Fortunately, it rarely is necessary to do an emergent bleeder as Pitressin usually provides temporary hemostasis.

Since bleeding from esophageal varices is a manifestation of underlying portal hypertension usually due to liver disease, therapy of the liver disease is most important. Often this will entail promoting abstinence from alcohol. Rarer forms of liver disease (hemochromatosis, Wilson's disease, and some forms of chronic active hepatitis) also have favorable responses to therapy.

Sclerotherapy for variceal hemorrhage is not a proved therapy at this time. It does reduce the rate of rebleeding, and it involves patients in an ongoing treatment program. Long-term effects on survival still are being evaluated.

RICHARD A. BAUM MD
University of Maryland Hospital

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Feast or Famine

In our society, eating habits vary, and food is often used as more than a source of nourishment. So we accept many individualized patterns.

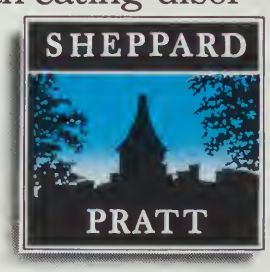
But some people go too far. The anorectic, threatened by food, slips into a pattern of self-imposed starvation. The bulimic, using food as a narcotic, binges and purges in an attempt to cope with overpowering emotions.

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The Use and Abuse of Cimetidine in a Gastroenterology Clinic

MAGALY RODRIGUEZ de BITTNER PharmD and FRANK IBER MD

Cimetidine is widely used for a variety of acid-pepsin gastrointestinal disorders, but because there are side effects on androgen-sensitive tissues and interference with other drugs, it should not be used at full dosage for periods exceeding three months. Our study demonstrated that a large number of patients are receiving the drug without further assessment of their gastrointestinal healing. Inappropriately prolonged administration at full dose was a problem in half the patients.

The authors are at the VA Medical Center, Baltimore, MD.

Cimetidine, a potent inhibitor of gastric acid formation, is proved effective in a number of circumstances in which peptic digestion occurs:

Healing of gastric ulcer
Healing of duodenal ulcer
Preventing recurrence of gastric or duodenal ulcer
Preventing stress ulcers
Relief and healing of reflux esophagitis
Medical treatment of Zollinger Ellison Syndrome
Facilitating action of pancreatic supplements

Although the agent has an excellent record of safety,[1,2] most studies used the agent short term (less than 3 months) in a full dose of 300 mg qid, and only limited studies of long-term effects are available. In males receiving 1 gm or more of cimetidine daily for one year, multiple side effects have occurred. These include antiandrogen effects such as decreased spermatogenesis, impotence, and gynecomastia. In both sexes, allergic reactions (including hepatitis or marrow suppression) are infrequent but possible side effects of the drug. Acute confusion is a toxic effect likely to occur in older persons having a life-threatening illness, taking multiple drugs, or having impaired renal function.

The number of adverse reaction reports secondary to cimetidine has increased, and the antiandrogenic ones are related to both dose and duration. In addition, cimetidine interacts with other commonly used agents such as warfarin, theophylline, diazepan, lidocaine, propranolol, and phenytoin.[3]

The apparent freedom from dramatic side effects over short courses has led to the use of cimetidine in many situations for which it is marginally indicated, and many reports have demonstrated this finding, including an excellent one from Baltimore.[4] The present study reviewed the use of cimetidine in a gastroenterology clinic, supervised by prominent community gastroenterologists and staffed by residents and trainees undertaking gastroenterology experience, to determine the use patterns by those with a great deal of experience with the drug.

Methodology

All patients in the Baltimore VA weekly gastroenterology clinic receiving cimetidine during the month of February 1984 were evaluated to determine appropriateness of cimetidine therapy. Appropriate therapy was determined by an audit criteria established by the clinical pharmacist in conjunction with the Chief of the Gastroenterology Section at the Baltimore VA Medical Center (Table 1). These criteria included Food and Drug Administration (FDA) approved indications, as well as literature-supported uses.

Each patient was evaluated from the clinical pharmacist's notes to determine whether the accepted criteria for cimetidine use were met for (a) indication for use, (b) duration of therapy, and (c) dose. In addition, information on correction of the systems and condition treated, side effects, and possible drug-drug interactions were recorded.

Results

During the study a total of 28 charts were available for review. Cimetidine was used for reflux esophagitis in the majority (32 percent) of the patients. Initial diagnosis was based on history and esophagoscopy. In most cases the drug was used for symptomatic relief, and no follow-up studies were performed to assess cure or drug therapy failure. Other indications were gastric ulcer (25 percent) and duodenal ulcer (25 percent) (Table 2, next page). Only these two indications are FDA approved.

Four patients reviewed were receiving cimetidine for epigastric pain without the appropriate diagnostic tests such as upper GI series or endoscopy. These patients were treated symptomatically for presumed duodenal ulcer.

In summary, cimetidine was given for FDA-approved indications in only 14 of the 28 patients reviewed (50 percent). The drug was used according to the established criteria in 83 percent.

Prolonged cimetidine therapy was the most common shortcoming found in this audit. Three months' use of

Table 1. Audit Criteria for Appropriate Use of Cimetidine

1. Was the diagnosis of an indicated use for cimetidine established by reasonable x-ray, endoscopy, and work-up for cimetidine?
2. Were the dosage and duration of treatment appropriate?
3. Were follow-up diagnostic tests performed to indicate healing or failure of the lesion to heal?
4. If cimetidine was continued after three or six months, was it used for an additional demonstrated responsive lesion or was it used prophylactically?

cimetidine was considered the maximum time for full-dose use (Table 3). Nineteen of the 28 patients (68 percent) exceeded this duration; 15 received the drug for longer than one year. Most of these patients were asymptomatic, and in some cases upper GI x-rays or endoscopy were repeated and showed healing, but the patients were maintained nonetheless on full cimetidine dose (300 mg qid).

Only 3 of the 28 patients evaluated were reduced to the prophylactic doses of 300 mg or 400 mg once daily at bedtime.

Side effects secondary to cimetidine therapy were documented in only one patient. In this patient sexual impotence was identified, and cimetidine treatment was discontinued (Table 4, next page).

Five patients were receiving four drugs that significantly interact with cimetidine therapy: warfarin, phenytoin, chlordiazepoxide, and theophylline.

Discussion

Results of this study show that cimetidine was used for appropriate indications in the majority of the patients studied (83 percent). However, a limited number of patients received the drug without an established diagnosis. This problem has been observed in previous studies[5,6] where cimetidine was given as a palliative measure to relieve the patient's abdominal complaints without further diagnostic procedures to determine the cause of these symptoms. Such use may delay diagnosis of serious problems such as gastric carcinoma, cholecystitis, or pancreatitis where different treatment might make a difference.

It is evident that cimetidine is effective for many indications beyond those recommended by the FDA, but it also is overused. Our results are similar to previously published studies[7,8] where cimetidine was used for non-FDA approved indications in half the cases.

Our most interesting finding is the duration of cimetidine use at full dose for an inappropriate period of time, usually longer than three months. This was often without further assessment and occasionally with appropriate assessment demonstrating the patient's condition was resolved. A few of our patients received the drug for three, four, and even five years (Table 3). This represents a significant problem for our patients because of the increased number of antiandrogen side effects and drug-drug interactions. The assessment of ulcer healing after an adequate eight to twelve weeks treatment with full cimetidine dose is essential. Then, the lower prophylactic dose of cimetidine (300 mg to 400 mg hs) can be used or the drug discontinued.

This study could not assess the magnitude of adverse drug reactions with prolonged cimetidine therapy, because only major complaints were recorded. While five patients were receiving drugs known to interact with cimetidine, documentation of these interactions and/or laboratory data to monitor these interactions were not available. In most cases these drug-drug interactions are significant and represent the effect of cimetidine in the liver enzymes.

Alternative Drugs

It is important to recognize safer alternative drugs exist that are essentially the same in therapeutic effect. These alternatives include antacids, ranitidine, and sucralfate.

Recently, ranitidine (Zantac®) was introduced in the U.S. market. This agent has been shown to be as effective as cimetidine in the treatment of ulcer and other similar conditions. Ranitidine is more potent than cimetidine on an equal gram basis and needs to be taken less frequently; it has fewer drug-drug interactions because of less effect on the liver enzymes and has total absence of antiandrogen effects. Although more costly each day, ranitidine possesses a very safe profile. Further long-term studies and clinical experience will determine the real safety of this agent. Recent reports of drug hepatitis have been reported with the use of ranitidine orally.[9,10]

Table 2. Indications in which Cimetidine Was Used

	Percent
Gastric ulcer	28
Duodenal ulcer	25
Reflux esophagitis	32
Epigastric pain	14
Bile gastritis	3

Table 3. Length of Cimetidine Therapy

	Number of Cases	
<3 months	8	"OK" by audit criteria
3 to 12 months	5	
1 year	4	Too long by audit
2 years	4	
3 years	3	
4 years	3	
5 years	1	

Antacids are effective in the treatment of peptic ulcer disease and are a very safe alternative to cimetidine treatment; some of them can be purchased over the counter. Antacids must be taken four to eight times daily, one and three hours after meals and at bedtime. They vary mostly in taste, cost, and effect on the bowels. Some agents contain harmful amounts of sodium (heart failure), calcium (stone formation) or aluminum and magnesium (renal failure).

Sucralfate (Carafate®) is a new class of drug (aluminum salt of sucrose sulfated) effective in treatment of peptic ulcer disease by coating the surface. It is described as a cytoprotective agent that binds selectively to the ulcerated mucosa protecting it from pepsin action. It also binds the bile salts and pepsin and is effective for ulcer at a dose of 1 gm qid, one hour before meals and at bedtime, for four to eight weeks treatment. The drug appears to be totally free of systemic side effects; constipation, the most common problem, is seen in 4 percent of the patients receiving the drug.[11] Lack of long-term studies as well as limited clinical experience with the drug have hindered the use of this agent. The drug's high cost also represents a disadvantage over cimetidine therapy.

Table 4. Side Effects and Potential Problems with Agents used in Ulcer Treatment

- Antacids
  - Frequent dosage
  - Poor compliance
  - Taste
  - Cost
  - Toxicity
    - Altered bowel function
    - Drug acid base or electrolyte imbalance
  - Drug interactions
- Cimetidine (Tagamet®)
  - Endocrine effects
    - Gynecomastia, oligospermia, hyperprolactinemia
  - Mental confusion
  - Bone marrow suppression
  - Drug-drug interaction
  - Cost
- Ranitidine (Zantac®)
  - Limited experience
  - Liver toxicity?
  - Cost
- Sucralfate (Carafate®)
  - Limited experience
  - Constipation
  - Cost

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BALANCED CALCIUM CHANNEL BLOCKADE!



Low incidence of side effects
CARDIZEM® (diltiazem HCl) produces an incidence of adverse reactions not greater than that reported with placebo therapy, thus contributing to the patient's sense of well-being.

*Cardizem is indicated in the treatment of angina pectoris due to coronary artery spasm and in the management of chronic stable angina (classic effort-associated angina) in patients who cannot tolerate therapy with beta-blockers and/or nitrates or who remain symptomatic despite adequate doses of these agents.

References:
1. Strauss WE, McIntyre KM, Parisi AF, et al: Safety and efficacy of diltiazem hydrochloride for the treatment of stable angina pectoris: Report of a cooperative clinical trial. Am J Cardiol 49:560-566, 1982.
2. Pool PE, Seagren SC, Bonanno JA, et al: The treatment of exercise-inducible chronic stable angina with diltiazem: Effect on treadmill exercise. Chest 78 (July suppl):234-238, 1980.

Reduces angina attack frequency*
42% to 46% decrease reported in multicenter study.[1]

Increases exercise tolerance*
In Bruce exercise test,[2] control patients averaged 8.0 minutes to onset of pain; Cardizem patients averaged 9.8 minutes ($P<.005$).

CARDIZEM®
(diltiazem HCl)

THE BALANCED CALCIUM CHANNEL BLOCKER

Please see full prescribing information on following page.

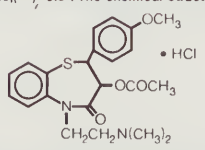
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PROFESSIONAL USE INFORMATION

cardizem®
(diltiazem HCl)
30 mg and 60 mg tablets

DESCRIPTION

CARDIZEM® (diltiazem hydrochloride) is a calcium ion influx inhibitor (slow channel blocker or calcium antagonist). Chemically, diltiazem hydrochloride is 1,5-Benzothiazepin-4(5H)one,3-(acetyloxy) -5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-, monohydrochloride,(+)-cis-. The chemical structure is:



Diltiazem hydrochloride is a white to off-white crystalline powder with a bitter taste. It is soluble in water, methanol, and chloroform. It has a molecular weight of 450.98. Each tablet of CARDIZEM contains either 30 mg or 60 mg diltiazem hydrochloride for oral administration.

CLINICAL PHARMACOLOGY

The therapeutic benefits achieved with CARDIZEM are believed to be related to its ability to inhibit the influx of calcium ions during membrane depolarization of cardiac and vascular smooth muscle.

Mechanisms of Action. Although precise mechanisms of its antianginal actions are still being delineated, CARDIZEM is believed to act in the following ways:

1. Angina Due to Coronary Artery Spasm: CARDIZEM has been shown to be a potent dilator of coronary arteries both epicardial and subendocardial. Spontaneous and ergonovine-induced coronary artery spasm are inhibited by CARDIZEM.
2. Exertional Angina: CARDIZEM has been shown to produce increases in exercise tolerance, probably due to its ability to reduce myocardial oxygen demand. This is accomplished via reductions in heart rate and systemic blood pressure at submaximal and maximal exercise work loads.

In animal models, diltiazem interferes with the slow inward (depolarizing) current in excitable tissue. It causes excitation-contraction uncoupling in various myocardial tissues without changes in the configuration of the action potential. Diltiazem produces relaxation of coronary vascular smooth muscle and dilation of both large and small coronary arteries at drug levels which cause little or no negative inotropic effect. The resultant increases in coronary blood flow (epicardial and subendocardial) occur in ischemic and nonischemic models and are accompanied by dose-dependent decreases in systemic blood pressure and decreases in peripheral resistance.

Hemodynamic and Electrophysiologic Effects. Like other calcium antagonists, diltiazem decreases sinoatrial and atrioventricular conduction in isolated tissues and has a negative inotropic effect in isolated preparations. In the intact animal, prolongation of the AH interval can be seen at higher doses.

In man, diltiazem prevents spontaneous and ergonovine-provoked coronary artery spasm. It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure and, in exercise tolerance studies in patients with ischemic heart disease, reduces the heart rate-blood pressure product for any given work load. Studies to date, primarily in patients with good ventricular function, have not revealed evidence of a negative inotropic effect; cardiac output, ejection fraction, and left ventricular end diastolic pressure have not been affected. There are as yet few data on the interaction of diltiazem and beta-blockers. Resting heart rate is usually unchanged or slightly reduced by diltiazem.

Intravenous diltiazem in doses of 20 mg prolongs AH conduction time and AV node functional and effective refractory periods approximately 20%. In a study involving single oral doses of 300 mg of CARDIZEM in six normal volunteers, the average maximum PR prolongation was 14% with no instances of greater than first-degree AV block. Diltiazem-associated prolongation of the AH interval is not more pronounced in patients with first-degree heart block. In patients with sick sinus syndrome, diltiazem significantly prolongs sinus cycle length (up to 50% in some cases).

Chronic oral administration of CARDIZEM in doses of up to 240 mg/day has resulted in small increases in PR interval, but has not usually produced abnormal prolongation. There were, however, three instances of second-degree AV block and one instance of third-degree AV block in a group of 959 chronically treated patients.

Pharmacokinetics and Metabolism. Diltiazem is absorbed from the tablet formulation to about 80% of a reference capsule and is subject to an extensive first-pass effect, giving an absolute bioavailability (compared to intravenous dosing) of about 40%. CARDIZEM undergoes extensive hepatic metabolism in which 2% to 4% of the unchanged drug appears in the urine. In vitro binding studies show CARDIZEM is 70% to 80% bound to plasma proteins. Competitive ligand binding studies have also shown CARDIZEM binding is not altered by therapeutic concentrations of digoxin, hydrochlorothiazide, phenylbutazone, propranolol, salicylic acid, or warfarin. Single oral doses of 30 to 120 mg of CARDIZEM result in detectable plasma levels within 30 to 60 minutes and peak plasma levels two to three hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3.5 hours. Desacetyl diltiazem is also present in the plasma at levels of 10% to 20% of the parent drug and is 25% to 50% as potent a coronary vasodilator as diltiazem. Therapeutic blood levels of CARDIZEM appear to be in the range of 50 to 200 ng/ml. There is a departure from dose-linearity when single doses above 60 mg are given; a 120-mg dose gave blood levels three times that of the 60-mg dose. There is no information about the effect of renal or hepatic impairment on excretion or metabolism of diltiazem.

INDICATIONS AND USAGE

1. **Angina Pectoris Due to Coronary Artery Spasm.** CARDIZEM is indicated in the treatment of angina pectoris due to coronary artery spasm. CARDIZEM has been shown effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (resting angina with ST-segment elevation occurring during attacks).
2. **Chronic Stable Angina (Classic Effort-Associated Angina).** CARDIZEM is indicated in the management of chronic stable angina. CARDIZEM has been effective in controlled trials in reducing angina frequency and increasing exercise tolerance.

There are no controlled studies of the effectiveness of the concomitant use of diltiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities.

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

1. **Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
2. **Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
3. **Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
4. **Acute Hepatic Injury.** In rare instances, patients receiving CARDIZEM have exhibited reversible acute hepatic injury as evidenced by moderate to extreme elevations of liver enzymes. (See PRECAUTIONS and ADVERSE REACTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS).

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vitro bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outweigh its potential risks in this situation.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences, as well as their frequency of presentation, are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%), AV block (1.1%). In addition, the following events were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrence.

Cardiovascular:	Flushing, arrhythmia, hypotension, bradycardia, palpitations, congestive heart failure, syncope.
Nervous System:	Paresthesia, nervousness, somnolence, tremor, insomnia, hallucinations, and amnesia.
Gastrointestinal:	Constipation, dyspepsia, diarrhea, vomiting, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH.
Dermatologic:	Pruritus, petechiae, urticaria, photosensitivity.
Other:	Polyuria, nocturia.

The following additional experiences have been noted:

A patient with Prinzmetal's angina experiencing episodes of vasospastic angina developed periods of transient asymptomatic asystole approximately five hours after receiving a single 60-mg dose of CARDIZEM.

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: erythema multiforme; leukopenia; and extreme elevations of alkaline phosphatase, SGOT, SGPT, LDH, and CPK. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

OVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with oral diltiazem has been limited. Single oral doses of 300 mg of CARDIZEM have been well tolerated by healthy volunteers. In the event of overdosage or exaggerated response, appropriate supportive measures should be employed in addition to gastric lavage. The following measures may be considered:

Bradycardia	Administer atropine (0.60 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.
High-Degree AV Block	Treat as for bradycardia above. Fixed high-degree AV block should be treated with cardiac pacing.
Cardiac Failure	Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics.
Hypotension	Vasopressors (eg, dopamine or levarterenol bitartrate).

Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating physician.

The oral LD_{50}'s in mice and rats range from 415 to 740 mg/kg and from 560 to 810 mg/kg, respectively. The intravenous LD_{50}'s in these species were 60 and 38 mg/kg, respectively. The oral LD_{50} in dogs is considered to be in excess of 50 mg/kg, while lethality was seen in monkeys at 360 mg/kg. The toxic dose in man is not known, but blood levels in excess of 800 ng/ml have not been associated with toxicity.

DOSAGE AND ADMINISTRATION

Exertional Angina Pectoris Due to Atherosclerotic Coronary Artery Disease or Angina Pectoris at Rest Due to Coronary Artery Spasm. Dosage must be adjusted to each patient's needs. Starting with 30 mg four times daily, before meals and at bedtime, dosage should be increased gradually (given in divided doses three or four times daily) at one- to two-day intervals until optimum response is obtained. Although individual patients may respond to any dosage level, the average optimum dosage range appears to be 180 to 240 mg/day. There are no available data concerning dosage requirements in patients with impaired renal or hepatic function. If the drug must be used in such patients, titration should be carried out with particular caution.

Concomitant Use With Other Antianginal Agents:

1. **Sublingual NTG** may be taken as required to abort acute anginal attacks during CARDIZEM therapy.
2. **Prophylactic Nitrate Therapy**—CARDIZEM may be safely coadministered with short- and long-acting nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.
3. **Beta-blockers.** (See WARNINGS and PRECAUTIONS.)

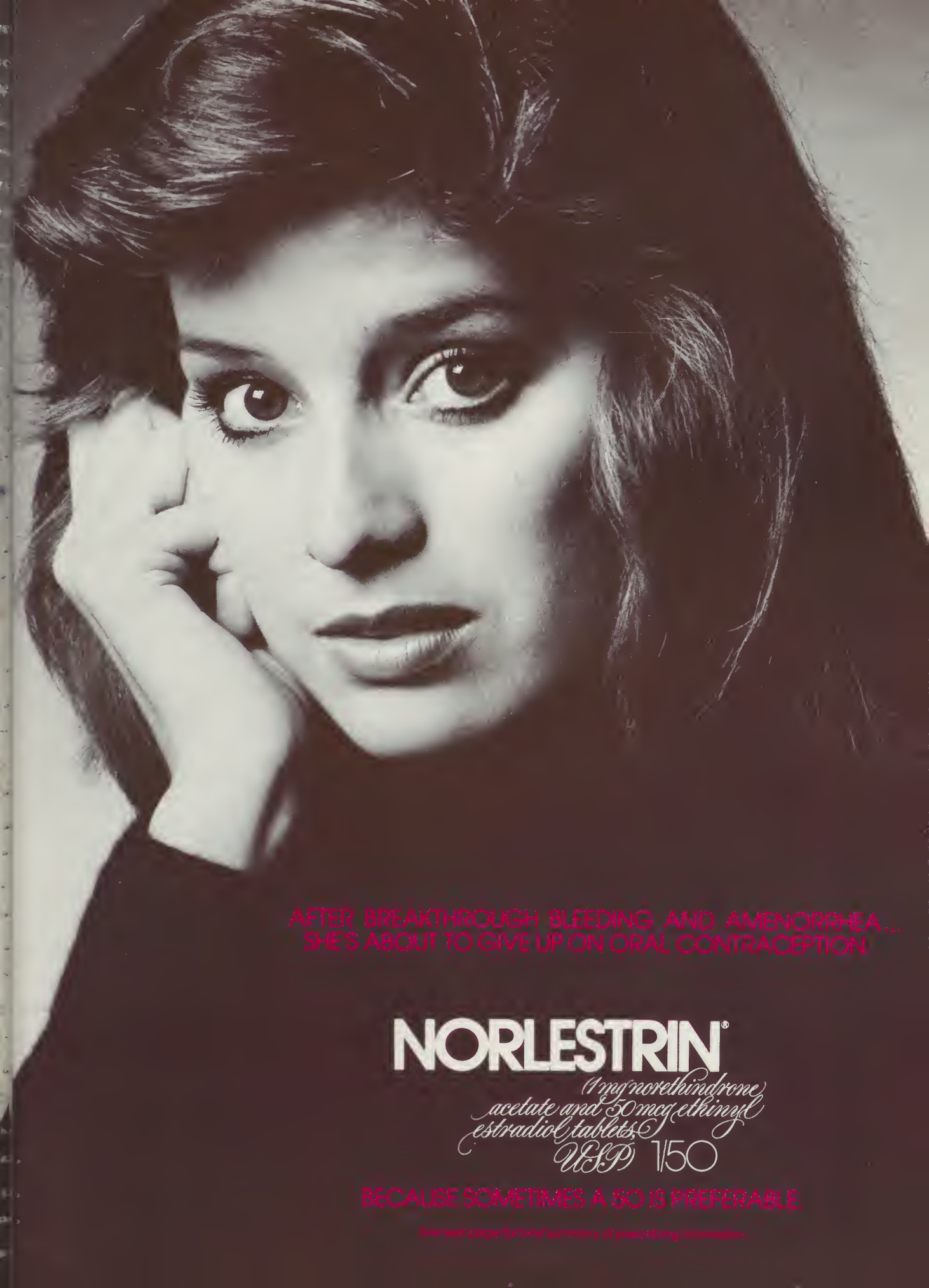
HOW SUPPLIED

Cardizem 30-mg tablets are supplied in bottles of 100 (NDC 0088-1771-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1771-49). Each green tablet is engraved with MARION on one side and 1771 engraved on the other. CARDIZEM 60-mg scored tablets are supplied in bottles of 100 (NDC 0088-1772-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1772-49). Each yellow tablet is engraved with MARION on one side and 1772 on the other.

Issued 4/1/84

Another patient benefit product from

PHARMACEUTICAL DIVISION
MARION LABORATORIES, INC.
KANSAS CITY, MISSOURI 64137


AFTER BREAKTHROUGH BLEEDING AND AMENORRHEA...
SHE'S ABOUT TO GIVE UP ON ORAL CONTRACEPTION.
NORLESTRIN®
1 mg norethindrone acetate and 50 mcg ethinyl estradiol tablets, USP 1/50
BECAUSE SOMETIMES A 50 IS PREFERABLE.
See next page for brief summary of prescribing information.

Brief Summary of Prescribing Information
NORLESTRIN® (norethindrone acetate and ethinyl estradiol tablets, USP)

See section under **Special Notes on Administration and HOW SUPPLIED.**
Before prescribing, please see full prescribing information. A Brief Summary follows.

DESCRIPTION
Norlestrin Products are progestogen-estrogen combinations.

INDICATIONS AND USAGE
Norlestrin Products are indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

In clinical trials with Norlestrin 1/50 involving 25,983 therapy cycles, there was a pregnancy rate of 0.05 per 100 woman-years; in clinical trials with Norlestrin 2 5/50 involving 96,388 cycles, there was a pregnancy rate of 0.22 per 100 woman-years.

Dose-Related Risk of Thromboembolism from Oral Contraceptives: Studies have shown a positive association between the dose of estrogens in oral contraceptives and the risk of thromboembolism. It is prudent and in keeping with good principles of therapeutics to minimize exposure to estrogen. The oral contraceptive prescribed for any given patient should be that product which contains the least amount of estrogen that is compatible with an acceptable pregnancy rate and patient acceptance.

CONTRAINDICATIONS
1. Thrombophlebitis or thromboembolic disorders
2. A past history of deep-vein thrombophlebitis or thromboembolic disorders
3. Cerebral vascular or coronary artery disease
4. Known or suspected carcinoma of the breast
5. Known or suspected estrogen-dependent neoplasia
6. Undiagnosed abnormal genital bleeding
7. Known or suspected pregnancy (See WARNING No. 5)
8. Benign or malignant liver tumor which developed during the use of oral contraceptives or other estrogen-containing products.

WARNINGS

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

The use of oral contraceptives is associated with increased risk of several serious conditions including thromboembolism, stroke, myocardial infarction, hepatic adenoma, gallbladder disease, and hypertension. Practitioners prescribing oral contraceptives should be familiar with the following information relating to these risks.

1. *Thromboembolic Disorders and Other Vascular Problems.* An increased risk of thromboembolic and thrombotic disease associated with the use of oral contraceptives is well-established. Studies have demonstrated an increased risk of fatal and nonfatal venous thromboembolism and stroke, both hemorrhagic and thrombotic.

Cerebrovascular Disorders: In a collaborative study in women with and without predisposing causes, it was estimated that the risk of hemorrhagic stroke was 2.0 times greater in users than nonusers, and the risk of thrombotic stroke was 4.0 to 9.5 times greater.

Myocardial Infarction: An increased risk of myocardial infarction associated with oral contraceptives has been reported confirming a previously suspected association. These studies found that the greater the number of underlying risk factors (cigarette smoking, hypertension, hypercholesterolemia, obesity, diabetes, history of preeclamptic toxemia) for coronary artery disease, the higher the risk of developing myocardial infarction, regardless of whether the patient was an oral contraceptive user or not. Oral contraceptives, however, were found to be a clear additional risk factor.

It has been estimated that users who do not smoke (smoking is considered a major predisposing condition to myocardial infarction) are about twice as likely to have a fatal myocardial infarction as nonusers who do not smoke. Oral contraceptive users who are smokers have about a fivefold increased risk of fatal infarction compared to users who do not smoke, but about a tenfold to twelvefold increased risk compared to nonusers who do not smoke. The amount of smoking is also an important factor.

Risk of Dose: In an analysis of data, British investigators concluded that the risk of thromboembolism, including coronary thrombosis, is directly related to the dose of estrogen used in oral contraceptives, however, the quantity of estrogen may not be the sole factor involved.

Persistence of Risk: Two studies have suggested that an increased risk may persist for as long as 6 years after discontinuation of oral contraceptive use for cerebrovascular disease and 9 years for myocardial infarction. In addition, a prospective study suggested the persistence of risk for subarachnoid hemorrhage.

Estimate of Excess Mortality from Circulatory Diseases: The risk of diseases of the circulatory system is concentrated in older women, in those with a long duration of use, and in cigarette smokers.

A study of available data from a variety of sources concluded that the mortality associated with all methods of birth control is low and below that associated with childbirth, with the exception of oral contraceptives in women over 40 who smoke.

The risk of thromboembolic and thrombotic diseases associated with oral contraceptives increases with age after approximately age 30 and, for myocardial infarction, is further increased by hypertension, hypercholesterolemia, obesity, diabetes, or history of preeclamptic toxemia, and especially by cigarette smoking.

The physician and the patient should be alert to the earliest manifestations of thromboembolic and thrombotic disorders. Should any occur or be suspected, the drug should be discontinued immediately.

A fourfold to sixfold increased risk of postsurgery thromboembolic complications has been reported in users. If feasible, oral contraceptives should be discontinued at least four weeks before surgery of a type associated with an increased risk of thromboembolism or prolonged immobilization.

2. *Ocular Lesions.* Neuro-ocular lesions, such as optic neuritis or retinal thrombosis, have been associated with the use of oral contraceptives. Discontinue the oral contraceptive if there is unexplained sudden or gradual, partial, or complete loss of vision; onset of proptosis or diplopia; papilledema; or retinal vascular lesions.

3. *Carcinoma.* Long-term continuous administration of estrogen in certain animal species increases the frequency of carcinoma of the breast, cervix, vagina, and liver.

In humans, an increased risk of endometrial carcinoma associated with the prolonged use of exogenous estrogen in postmenopausal women has been reported. However, there is no evidence suggesting increased risk of endometrial cancer in users of conventional combination or progestogen-only oral contraceptives.

Studies found no evidence of increase in breast cancer in women taking oral contraceptives; however, an excess risk in users with documented benign breast disease was reported.

There is no confirmed evidence of an increased risk of cancer associated with oral contraceptives. Close clinical surveillance of users is, nevertheless, essential. In cases of undiagnosed persistent or recurrent abnormal vaginal bleeding, appropriate diagnostic measures should be taken to rule out malignancy. Women with a strong family history of breast cancer, or who have breast nodules, fibrocystic disease, or abnormal mammograms, should be monitored with particular care.

4. *Hepatic Tumors.* Benign hepatic adenomas have been found to be associated with oral contraceptives. Because hepatic adenomas may rupture and may cause death through intra-abdominal hemorrhage, they should be considered in women presenting abdominal pain and tenderness, abdominal mass, or shock.

A few cases of hepatocellular carcinoma have been reported in women taking oral contraceptives. The relationship of these drugs to this type of malignancy is not known at this time.

5. *Usage in or Immediately Preceding Pregnancy; Birth Defects in Offspring, and Malignancy in Female Offspring.* During early pregnancy, female sex hormones may seriously damage the offspring.

An increased risk of congenital anomalies, including heart defects and limb defects, has been reported with the use of oral contraceptives in pregnancy.

There is some evidence that triploidy and possible other types of polyploidy are increased among abortuses from women who become pregnant soon after ceasing oral contraceptives.

Pregnancy should be ruled out before continuing an oral contraceptive in any patient who has missed two consecutive menstrual periods. If the patient has not adhered to the schedule, the possibility of pregnancy should be considered at the time of the first missed period and oral contraceptives should be withheld until pregnancy has been ruled out. If pregnancy is confirmed, the patient should be apprised of the potential risks to the fetus and the advisability of continuation of the pregnancy should be discussed.

Women who discontinue oral contraceptives with the intent of becoming pregnant should use an alternate form of contraception for a period of time before attempting to conceive.

Administration of progestogen-only or progestogen-estrogen combinations to induce withdrawal bleeding should not be used as a test of pregnancy.

6. *Gallbladder Disease.* Studies report an increased risk of surgically confirmed gallbladder disease in users of oral contraceptives.

7. *Carbohydrate and Lipid Metabolic Effects.* Because decreased glucose tolerance has been observed in a significant percentage of patients, prediabetic and diabetic patients should be carefully observed while receiving oral contraceptives.

An increase in triglycerides and total phospholipids has been observed.

8. *Elevated Blood Pressure.* An increase in blood pressure has been reported in patients receiving oral contraceptives. The prevalence in users increases with longer exposure. Age is also strongly correlated with development of hypertension. Women who previously have had hypertension during pregnancy may be more likely to develop elevation of blood pressure.

9. *Headache.* Onset or exacerbation of migraine or development of headache of a new pattern which is recurrent, persistent, or severe, requires discontinuation of oral contraceptives.

10. *Bleeding Irregularities.* Breakthrough bleeding, spotting, and amenorrhea are frequent reasons for patients discontinuing oral contraceptives. In breakthrough bleeding, nonfunctional causes should be borne in mind. In undiagnosed abnormal bleeding from the vagina, adequate diagnostic measures are indicated to rule out pregnancy or malignancy.

Women with a past history of oligomenorrhea or secondary amenorrhea, or young women without regular cycles should be advised that they may have a tendency to remain anovulatory or to become amenorrheic after discontinuation of oral contraceptives.

11. *Ectopic Pregnancy.* Ectopic as well as intrauterine pregnancy may occur in contraceptive failures.

12. *Breast-Feeding.* Oral contraceptives may interfere with lactation. Furthermore, a small fraction of the hormonal agents in oral contraceptives has been identified in the milk of mothers receiving these drugs.

PRECAUTIONS

1. A complete medical and family history should be taken prior to the initiation of oral contraceptives. The pretreatment and periodic physical examinations should include special reference to blood pressure, breasts, abdomen, and pelvic organs, including Papanicolaou smear and relevant laboratory tests. As a general rule, oral contraceptives should not be prescribed for longer than one year without another examination.

2. Preexisting uterine leiomyomata may increase in size.

3. Patients with a history of psychic depression should be carefully observed and the drug discontinued if depression recurs to a serious degree.

4. Oral contraceptives may cause fluid retention and should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated.

5. Patients with a past history of jaundice during pregnancy have an increased risk of recurrence of jaundice. If jaundice develops, the medication should be discontinued.

6. Steroid hormones may be poorly metabolized and should be administered with caution in patients with impaired liver function.

7. Users may have disturbances in normal tryptophan metabolism, which may result in a relative pyridoxine deficiency.

8. Serum folate levels may be depressed.

9. The pathologist should be advised of oral contraceptive therapy when relevant specimens are submitted.

10. Certain endocrine and liver function tests and blood components may be affected.

(a) Increased sulfobromophthalein retention. (b) Increased prothrombin and factors VII, VIII, IX, and X; decreased antithrombin 3; increased norepinephrine-induced platelet aggregability. (c) Increased thyroid-binding globulin (TBG) leading to increased circulating total thyroid hormone. (d) Decreased pregnanediol excretion. (e) Reduced response to metyrapone test.

Drug Interactions: Reduced efficacy and increased incidence of breakthrough bleeding have been associated with concomitant use of rifampin. A similar association has been suggested with barbiturates, phenylbutazone, phenytoin sodium, tetracycline, and ampicillin.

ADVERSE REACTIONS
An increased risk of the following serious adverse reactions has been associated with oral contraceptives: thrombophlebitis; pulmonary embolism; coronary thrombosis; cerebral thrombosis; cerebral hemorrhage; hypertension; gallbladder disease; benign hepatomas; congenital anomalies.

There is evidence of an association between the following conditions and the use of oral contraceptives, although additional confirmatory studies are needed: mesenteric thrombosis; neuro-ocular lesions, eg, retinal thrombosis and optic neuritis.

The following adverse reactions have been reported in patients receiving oral contraceptives and are believed to be drug related: nausea and/or vomiting, usually the most common adverse reactions, occur in approximately 10% or less of patients during the first cycle. Other reactions, as a general rule, are seen much less frequently or only occasionally: gastrointestinal symptoms; breakthrough bleeding; spotting; change in menstrual flow; dysmenorrhea; amenorrhea during and after treatment; temporary infertility after discontinuance of treatment; edema; chloasma or melasma; breast changes; change in weight; change in cervical erosion and cervical secretion; possible diminution in lactation when given immediately postpartum; cholestatic jaundice; migraine; increase in size of uterine leiomyomata; rash (allergic); mental depression; reduced tolerance to carbohydrates; vaginal candidiasis; change in corneal curvature; intolerance to contact lenses.

The following adverse reactions have been reported and the association has been neither confirmed nor refuted: premenstrual-like syndrome; cataracts; changes in libido; chorea; changes in appetite; cystitis-like syndrome; headache; nervousness; dizziness; hirsutism; loss of scalp hair; erythema multiforme; erythema nodosum; hemorrhagic eruption; vaginitis; porphyria.

Special Notes on Administration
Menstruation usually begins two or three days, but may begin as late as the fourth or fifth day, after discontinuing medication.

After several months on treatment, bleeding may be reduced to a point of virtual absence; reduced flow may be a result of medication and not indicative of pregnancy.

HOW SUPPLIED
Norlestrin [21] 1/50 is available in compacts each containing 21 tablets. Each tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

Norlestrin [21] 2 5/50 is available in compacts each containing 21 tablets. Each tablet contains 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

Norlestrin [Fe] 1/50 is available in compacts each containing 21 yellow tablets and 7 brown tablets. Each yellow tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Each brown tablet contains 75 mg of ferrous fumarate, USP. Available in packages of five compacts and packages of five refills.

Norlestrin [FE] 2.5/50 is available in compacts each containing 21 pink tablets and 7 brown tablets. Each pink tablet contains 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Each brown tablet contains 75 mg of ferrous fumarate, USP. Available in packages of five compacts and packages of five refills.

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Osteoarthritis VII: Rheumatic Disease in the Elderly

MARY BETTY STEVENS MD

Aging imposes rheumatologic hazard on individuals with medical and psychosocial problems that limit their physical activity and socialization. Musculoskeletal pain and stiffness can occur, with the eventual loss from disuse of muscle tone, bulk, and strength. Clues to such *nonorganic* syndromes may be subtle but focus on environmental factors, integrity of a patient's support system and, clinically, a dissociation between symptoms and signs. Pain syndromes often are diffuse, variable over time, and resistant to usual conservative measures and NSAID therapy. Diagnoses must be approached with caution only after careful exclusion of other treatable disorders.

Dr. Stevens, an Associate Professer of Medicine, is Director, Rheumatology Division, The Johns Hopkins University School of Medicine, Baltimore, MD

From the diagnostic viewpoint, the high prevalence of osteoarthritis radiographically, and the changing serologic profiles can distract the physician faced with the elderly patient's rheumatic complaints. Errors in clinical problem solving often arise from assuming a relationship between a musculoskeletal syndrome and the presence of x-ray change or serum autoantibodies (especially "rheumatoid" or anti-IgG factors) that can be found in the majority of those over age 65. The aging process itself can lead to rheumatic complaints not only through loss of physical activity and musculoskeletal disuse but also from nonorganic, functional syndromes in those who are depressed or lack an adequate support system.

Therapeutically, drugs can pose added and different problems than in the young patient. Drug interactions assume greater potential significance in the older group with its increased medical problems and required polypharmacy. Host response to administered drugs may vary; in those with diminished organ function (for example, hepatorenal) or altered capacity for drug binding (for example, hypoalbuminemia), appropriate dose adjustments must be made. Patient compliance often requires special attention to the capacity of the elderly patient to follow a regimen and to the support system available to assure compliance.

Finally, those rheumatic disorders generally associated with the young adult can surface in the elderly. Demographic features other than age and clinical expression of such "young adult diseases" as rheumatoid arthritis or systemic lupus may be modified in the patient of advanced age.

Thus, rheumatic disorders in the older group can pose problems that must be approached with special caution and concern. Shown in Table 1 are the prominent disorders of the elderly, emphasizing prevalent syndromes with major therapeutic implications. It is the purpose here to emphasize rheumatic disorders emerging or having special implication in the elderly.

Table 1. Rheumatic Disease in the Elderly*

Articular	Osteoarthritis
	Microcrystalline synovitis
	Septic arthritis
Systemic	Polymyalgia rheumatica
	Arteritis (esp. GCA)
	Polymyositis
	Sjogren's syndrome

* Tumor and drug-related syndromes, osteoporosis, and late-onset "young" disease are also prominent.

Articular Disorders

As in the young adult, multiple incitants including microcrystals, infectious organisms, and immune complexes can evoke an intense synovial response in the elderly patient. The inflammatory reaction to foreign bodies and shredded fibrils arising from degenerative joint disease or trauma is less marked. Similarly, tumor-related arthritis is less intense at the synovial fluid level although, clinically, it can mimic rheumatoid arthritis and even gout.

Microcrystalline arthritis Calcium pyrophosphate dihydrate deposition disease (CPPD or pseudogout) is the typical microcrystalline disorder of the elderly, although the first attack of gout can occur as late as the eighth decade. Secondary gout, especially drug induced, is particularly prominent in the older group. Nonfamilial CPPD increases with advancing age but seldom appears before age 50 unless associated with a predisposing genetic (for example, hemochromatosis, Wilson's disease) or metabolic (hyperparathyroidism, hypothyroidism disorders.

Regardless of crystal chemistry, the hallmarks of microcrystalline synovitis include abruptness of onset, extreme intensity of inflammatory reaction, episodicity, and recurrent attacks with symptom-free intervals. While a monarticular arthritis is typical at onset, in the older individual especially, both gout and CPPD may present a more indolent, chronic, polyarthritis that mimics rheumatoid arthritis. Despite the association of hyperuricemia with gout and articular chondrocalcinosis with pseudogout, certain diagnosis rests with synovial fluid examination (Table 2). The leucocytosis is

Table 2. Synovial Fluid

	CPPD Gout	Septic	Osteo-arthritis
Grossly turbid	+	+	–
Low viscosity	+	+	–
High WBC (PMNs)	+	+	–
Low glucose	–	+	–
Microscopic	crystals	organism*	fibrils

* culture (+) > smear (+)

brisk (WBC ≥ 10,000) with more intracellular than extracellular crystals after the first several hours.

Whether the acute episode is initiated in the synovial fluid or in the synovium is not entirely clear. The recent demonstration of prostaglandin release by cultured synovial macrophages after exposure to microcrystals suggests the latter; this would help explain the initial ingress of leucocytes into the synovial fluid phase.

While mechanisms of crystal-induced synovitis may be similar in gout and pseudogout (or CPPD), the two disorders differ clinically in both acute and chronic phases. In gout, the acute attack has a greater periarticular, soft-tissue component, so marked in some that thrombophlebitis or cellulitis is suggested initially. In pseudogout, the acute episode is clearly an intra-articular process with periarticular inflammation minimal or lacking. In their chronic forms, both microcrystalline disorders may appear "rheumatoidlike," especially in the elderly individual. However, pseudogout can be particularly difficult to distinguish clinically from rheumatoid arthritis in those frequent instances when a history of acute attacks is lacking and the synovial changes involve predominantly metacarpophalangeal joints and wrists.

Septic arthritis While articular sepsis occurs at any age and has no special predilection for the elderly, the enormous therapeutic implication of septic arthritis demands its inclusion here. Although the absolute diagnosis is established by synovial fluid examination (Table 2), the essential first step is to suspect the presence of infection; in the elderly, the frequently blunted systemic response to infection may divert attention from an infectious process. The clues to septic arthritis are the character of joint involvement, and the overall clinical setting.

Typically, septic arthritis is a monarticular, intensely inflammatory process that can involve any joint, axial or (more frequently) peripheral. It can be difficult, if not impossible, to distinguish the septic joint from acute microcrystalline synovitis on clinical grounds alone, due to overlap in their patterns of joint involvement. However, a history of recurrent similar episodes, characteristic of gout and pseudogout, is most helpful. Equally important is the historical and/or physical evidence for factors that predispose the elderly patient to secondary gout (for example, diuretic therapy, associated disease) and infection (Table 3). Certain factors predisposing to infection can modify the pattern of joint involvement and favor a polyarticular presentation: an underlying chronic synovitis (especially rheumatoid arthritis) or intra-articular foreign body or anti-inflammatory therapy (especially corticosteroids) can mask inflammation and delay diagnosis.

With reliance on nonsteroidal anti-inflammatory drugs (NSAIDs) in acute gout and pseudogout, in contrast to organism-specific antibiotics for the infected joint, the need for specific diagnosis is obviously great.

Systemic Disorders

A unique and increasingly recognized syndrome of the elderly is *polymyalgia rheumatica (PMR)*, a term coined by Barber in 1957 to describe proximal limb-girdle and cervical musculoskeletal pain and stiffness. Pain is the dominant early manifestation often erroneously diagnosed as cervical, shoulder, or hip osteoarthritis because of the prevalent radiographic changes in the elderly patient. Careful clinical evaluation usually can establish the diagnosis of PMR with its bilaterality, coupled with absence of neurologic abnormalities or evidence of intrinsic joint and muscle disease. Nonetheless, in our earlier series, delay in diagnosis from onset of symptoms averaged ~11 months.

Constitutional symptoms (for example, low-grade fever, weight loss), weakness, and articular inflammation can be part of the PMR syndrome. The arthritis is interesting in its central joint pattern with sternoclavicular and acromioclavicular involvement. Shoulders, hips, and wrists (with associated carpal tunnel syndrome) frequently are involved especially when defined by scanning techniques that can show increased isotope uptake even in the absence of clinical signs of articular inflammation.

A markedly increased sedimentation rate, not otherwise explained, is the key laboratory abnormality present in the vast majority and serves as a criterion for diagnosis. The response to corticosteroids (prednisone 20 to 40 mg daily or equivalent) is so prompt (within 24 to 48 hours) and complete that it is used by some as a confirmatory diagnostic feature.

The implications of PMR extend well beyond the musculoskeletal pain and disability that, without treatment, persist and progress. While PMR occurs alone most commonly, it should properly be recognized as a syndrome that can, in a few cases, represent a prodrome of rheumatoid arthritis or a tumor-related manifesta-

Table 3. Septic Arthritis: Predisposing Factors

Focus of infection
Antecedent procedure/exposure
Valvular cardiac disease
Articular abnormality
chronic synovitis
prosthesis
Drug therapy
corticosteroid
cytotoxic

tion and more frequently, a phase of *giant cell arteritis (GCA).*

In an older patient (especially Caucasian and female) with PMR, the occurrence of cephalic symptoms signals the presence of GCA. Temporal cephalgia (unilateral or bilateral), scalp tenderness, and jaw claudication are common; on examination, temporal artery tenderness and an absent or diminished pulse may be present. Of most concern are the visual changes; history of one or more fleeting episodes of visual loss (amaurosis fugax) is an indication for immediate high-dose corticosteroid therapy (prednisone ≥50 mg daily or equivalent). Over half the patients with PMR and cephalic manifestations will have GCA demonstrated on temporal artery biopsy as will ~20 to 30 percent of those with symptomatic PMR alone. However, in view of the tissue-sampling problem of a segmentally involved artery, biopsy negativity should not argue against appropriate corticosteroid therapy.

In the elderly patient with a proximal limb-girdle musculoskeletal syndrome (pain and/or weakness), the diagnosis often is reduced to PMR versus *polymyositis.* As shown in Table 4, differentiation between them generally is not difficult, especially when typical skin lesions (for example, Gottron's papules, heliotrope eyelids, vasculitis) accompany the inflammatory myopathy. In contrast to PMR, the dominant clinical expression of polymyositis (PM) is muscle weakness, with pain and tenderness relatively infrequent and mild even in patients with florid inflammation on muscle biopsy. The sedimentation rate can be normal in such patients; the increased serum level of one or more muscle enzymes (CPK, SGOT, SGPT, aldolase) provides the laboratory basis for diagnosis and monitoring response to suppressive therapy.

The implications of PM clinically include more than the consequences of a musculoskeletal syndrome. The key issue is whether PM (with or without skin lesions) occurs alone, in the setting of a multisystem connective tissue disorder (for example, systemic lupus, systemic sclerosis, Sjogren's), or in association with neoplasm. Tumor-related PM emerges in the older group; thus, the occurrence of PM in a patient over age 50 demands a reasonable search for neoplasm, specifically solid tumors rather than lymphoid or hematologic malignancies. The presence of typical skin lesions (that is, dermatomyositis), peripheral vasculitis, or profound weight loss and nonhemolytic anemia may increase the likelihood of an occult tumor. Conversely, the presence of Raynaud's phenomenon, other connective tissue disease features, or seropositivity (for example, ANAs, anti-Jo-l, anti-Ro/La) argue against tumor-related PM. Especially in elderly patients with PM, thorough clinical and serologic assessment is essential if the few with PM signalling an occult malignancy are to be diagnosed early and treated appropriately with antitumor therapy as well as corticosteroids.

Table 4. PMR vs PM

	PMR	PM
Proximal limb/girdle		
Pain, stiffness	++	+
Weakness	+	++
Tenderness	−	+
Elevated muscle enzymes	−	++
Elevated sedimentation rate	++	+
Abnormal electromyogram	−	++
Tissue biopsy		
Skeletal muscle	−	++
Temporal artery	+	−

Myositis is a less frequent extraglandular feature of *Sjogren's syndrome*; and in recent years, there has been increased awareness of the systemic manifestations of this immunologic disorder so prominent in elderly women. The classical feature of Sjogren's is its sicca complex (that is, xerophthalmia and/or xerostomia) with lack of tear and saliva production reflecting lacrimal and salivary gland failure due to extensive glandular infiltrates of immunocompetent lymphocytes. Rose Bengal staining of the cornea confirms the erosions (that is, keratoconjunctivitis sicca) due to chronic loss of tears and constitutes a valuable diagnostic test. However, most specific and sensitive is the lip biopsy of minor salivary glands that, like the parotids and submandibulars, are infiltrated.

Much interest and study have focused on the spectrum of Sjogren's syndrome relative to its clinical setting and extraglandular features and its immunogenetic profile. The sicca complex often can occur alone in the elderly population. In contrast, it can emerge in the setting of an established, well-defined immunologic disorder such as rheumatoid arthritis, systemic lupus, or (less frequently) other connective tissue disease. Rarely does the sicca syndrome antedate these associated disorders in the older adult. Between these two extremes are those patients with focal or diffuse sicca manifestations associated with one or more systemic, extraglandular features but without criteria satisfied for a concomitant diagnosis. The classical subsetting of this autoimmune disorder into *primary* (that is, without associated disease) versus *secondary* (that is, with an associated rheumatic disorder) fails to emphasize the clinical dimension or complexities of Sjogren's.

Regardless of clinical setting, the sicca component of Sjogren's may be diffuse with dryness of the bronchorespiratory tree, diminished gastric secretion with

achlorhydria, and sicca vaginitis. Although in secondary Sjogren's the features of the associated disorder are dominant, patients with primary Sjogren's may have Raynaud's phenomenon, "rheumatoidlike" but less erosive polyarthritis, myositis, cutaneous and/or systemic vasculitis, pleuropulmonary lesions, or central and peripheral neuropathies. Although the Sjogren-related Ro(SSA)/La(SSB) autoantibody system is neither specific nor sensitive for the diagnosis of Sjogren's, anti-Ro(SSA) appears to correlate closely with the presence of vasculitis in these patients. Furthermore, hematologic abnormalities and seroreactivity (that is, hyperglobulinemia, rheumatoid, and non-dsDNA antinuclear factors, cryoglobulins) are significantly more prevalent in the anti-Ro(SSA) positive subset.

Thus, in addition to the local management of the membrane manifestations of the sicca complex, the potential of systemic illness must be recognized along with increased risk of lymphoma in a few.

Other Clinical Issues

A common problem in the elderly, especially women and those who are physically inactive, is *osteoporosis*, which increases in prevalence with age. The presence of a chronic inflammatory synovitis (for example, rheumatoid arthritis) and/or chronic corticosteroid therapy increases the likelihood and severity of this demineralization of bone. Clinical problems arise from the pathologic fractures occurring not only peripherally following minimal trauma but also in the axial skeleton (that is, vertebral compression fractures). However, such lesions can only be attributed to the idiopathic osteoporosis of aging after the careful exclusion of added underlying bone pathology such as solid tumor metastases or multiple myeloma.

The rheumatic manifestations of *malignant neoplasia* are varied; in the older group, the possibility of a tumor-related process must be considered in the setting of muscle pain and weakness, bone pain and pathologic fracture, and articular syndromes. A rheumatoidlike polyarthritis of abrupt onset occurs infrequently and, in some patients, is associated with acute clubbing of the nails and periostitis of the long bones (that is, Marie Bamberger syndrome). The periarticular sites of metastases, as in the pelvis, may mimic an arthritis.

The presence of significant constitutional symptoms (such as unexplained fever and/or weight loss) lends emphasis not only to a possible neoplastic process but also *connective tissue disease* and indolent infection or dysmetabolism. Of particular interest are the variants of polyarteritis. The systemic features of the elderly's temporal or giant cell arteritis (GCA) are usually mild with low-grade fever and a weight loss only occasionally impressive in degree. However, classical polyarteritis can begin in later life and should be suspect in individuals (especially men) with unexplained fever, weight loss, and minor rheumatic complaints as well as in those with typical multisystem disease (for example, musculoskeletal pain, cutaneous vasculitis, peripheral neuropathy, and nephritis with hypertension). Similarly, the granulomatous arteritis of Wegener or the serum sickness of drug/protein-induced angiitis can emerge in the elderly and are of major therapeutic importance.

Equally varied in clinical problems are the iatrogenic or *drug-induced* rheumatic syndromes. Their recognition leads directly to withdrawal of the offending agent and "cure" of the rheumatic disorder. The polypharmacy of medical need(s) of the elderly targets them for such disorders. Secondary gouty arthritis related to diuretics or pronestyl-induced lupus are examples of rheumatic disorders that, in prevalence, parallel the use of drugs. Thus the elderly patient with cardiovascular problems is at high risk. An encyclopaedic listing of adverse reactions is impossible here, but the principle of meticulous assessment of an emerging rheumatic syndrome in light of administered drug therapy, especially in patients of advanced age, deserves emphasis.

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Inside Med-Chi

Committee on Physician Rehabilitation

The history and background of the Committee on Physician Rehabilitation were told in the October 1980 *Maryland State Medical Journal.* Much has happened since those beginnings, and a lot of progress has been made. At present, the medical society of every state has a similar program, and each has its individual mode of operation. We are fortunate in Maryland to have one of the most progressive and effective committees in existence, largely through the efforts of a group of dedicated physician volunteers but also through the moral and financial support of all members of the medical society. As the staff member who has worked with this committee since its inception, I am proud to have been associated with a program of such far-reaching, positive results. The devotion and caring attitude of these volunteer physicians has made a lasting impression on me and, I am sure, on everyone whose lives they have touched.

Outlined briefly here is the process followed by the committee to assure that physicians who have addictive diseases or emotional or psychiatric illnesses receive appropriate treatment to enable them to return to productive practices.

A Hotline number (727-0120) provides a direct connection to the office of the Med-Chi staff person working with the committee. A recorder will take messages for after-hours calls. Anyone wishing to report a physician who may be impaired may call the Hotline, giving the information that led to the caller's concern. The caller may remain anonymous; however, identification will be requested, as well as any additional information that may be helpful to the committee in verifying that the physician reported is indeed ill and that the call is neither frivolous or vindictive. Then the committee goes to work.

If, after discreet inquiries are made, the report appears confirmed, the process is begun to see that the physician obtains the most appropriate and effective treatment available. First, the committee sends a letter expressing its concern and advising the physician that his colleagues wish to meet with him. A "contact team" is informed of the nature of the physician's problem but not the name of the reporter. In the case of addictive diseases, at least one of the team members will be recovering from that illness. In the case of psychiatric or emotional illness, at least one of the team members will be a psychiatrist. Contact teams are compassionate, nonjudgmental, and supportive of the ill physician. It is the intent of the committee to act as advocate of each physician reported.

Public Relations Committee
James E. Bell MD, Chairman

There are occasions (although rare) when the contact team finds as a result of its visit there is no evidence of addiction or psychiatric illness. In such cases, the physician will be informed of the committee's opinion, and the case will be closed without prejudice.

If, on the other hand, the contact team verifies there is evidence the physician is impaired due to the use of drugs or alcohol, a defined course of treatment will be recommended. If a physician needs emergency psychiatric consultation (that is, he is potentially suicidal), arrangements will be made for him to be seen immediately by a psychiatrist recommended by the committee.

When the immediate course of treatment is completed, the physician is not abandoned. The committee prescribes continuing aftercare for two years and will monitor his progress throughout that period. Individual members of the committee act as one-to-one monitors, keeping in contact with the physician for support and assuring him of the continuing concern for him.

Physician Resistance

There are occasions when a physician, determined by the contact team to be impaired by use of drugs or alcohol or by psychiatric illness, refuses to accept treatment or to cooperate with the committee. A second contact team will attempt to clarify the need for treatment. It is well known that physicians impaired due to addictive illnesses usually do not seek help on their own for several reasons. Denial is the most common reason and the one most difficult to overcome. However, many cannot comprehend the seriousness of their illness; are fearful of loss of license, income, or professional esteem; or have other reasons known only to themselves.

When a physician continues to resist all efforts of assistance, the committee faces a difficult decision. They have a responsibility to their colleagues and to the public to see that impairment of any kind is not reflected in the practice of medicine. Therefore, if a physician firmly and finally refuses the assistance of the committee, the Med-Chi Peer Review Committee will be requested to conduct a comprehensive review of his practice. If the committee believes the physician is so ill that he presents a danger to either himself or others, he will be reported directly to the Commission on Medical Discipline. This is a step not lightly taken, but one that must be considered in order to protect the integrity of the committee and the medical society.

The committee has been in existence for seven years. In that time, more than two hundred physicians have been seen by the committee. Approximately half have been evaluated and have undergone or are undergoing treatment. Since alcohol and other drug dependency

historically has a high rate of recidivism, this 50 percent mark of recovery is exceptional. The remaining 50 percent include those who have refused assistance or have returned to abuse; those who have retired, left the state, or died; are unconfirmed; or have been referred to Peer Review. (Although reference in this article has been to masculine gender, female physicians comprise approximately 9 percent of those reported.)

One thing that distinguishes this committee from most other society endeavors is its loan program. Members of the medical society have been most generous in assessing themselves to allow the committee to carry out a unique loan program. Physicians who might forego needed treatment because of financial difficulties may be granted a loan by the committee, interest free, with initial repayment delayed until one year later. About 30 physicians have benefited from this program in the past, with loans from $500 to more than $8,000, and many more will take advantage of it in the future. The members of this medical society have demonstrated a practical sense of responsibility and empathy for which the committee is grateful.

The Faculty recently hired a Coordinator to work part time with the committee to allow for its further growth. Robert Kane White, a Certified Alcoholism Counselor with a Master's Degree in Community/Clinical Psychology, will assist in the initial evaluation of physicians reported to the committee, help families cope with associated problems, establish communications with component and specialty societies and hospital medical staffs, and assist in preparing statistical reports documenting the endeavors of the committee.

The AMA strongly supports programs throughout the country directed toward assisting the impaired physician. At the Sixth National Conference on the Impaired Physician held recently in New Jersey, experts in the field of addiction gathered for three days of consultation and exchange of information. Med-Chi committee members and staff were active participants. We constantly add to our knowledge and gain experience in a field that is ever changing and yet never changes.

I end this article by reiterating Dr. Jerome Coller's plea of October 1980: "If this issue of our *Journal* leaves you with nothing else, carry away two bits of information: (1) the impaired physician suffers from a disease . . . not a lack of moral fiber . . . and, if unchecked . . . progresses to professional and social ruin and often death, and (2) with early intervention and a 'tough love' treatment program, the result can be total recovery."

CONSTANCE E. TOWNSEND
Assistant to the Executive Director

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Members in the News

Philip Heuman MD, Bel Air, received a "living treasure" award for his 31 years of service to Harford County in the practice of family medicine. A resident of the county for all those years, Dr. Heuman held such distinguished titles as Assistant and Chief of the Medical Examiners Office, Director of the Obstetrics Department of the Harford County Health Department, and team physician for the Bel Air Bobcats.

• • •

Perry Hookman MD, Cheverly, was reelected as a Governor of the American College of Gastroenterology for the State of Maryland at the College's recent Annual Meeting in Toronto. As a Governor, Dr. Hookman represents College members in Maryland on the Board of Governors, an administrative body of the College composed of Governors throughout the United States, Canada, and other countries. Dr. Hookman was also elected Vice-Chairman of the Board of Governors at its recent organizational meeting.

James E. Taylor MD, associate pathologist at St. Agnes Hospital, is president of the St. Agnes Hospital Medical Staff, having served a one-year term as president-elect.

Dr. Taylor, a resident of Timonium, received his BS degree from the University of Maryland and his Medical Degree from the University of Maryland School of Medicine. He served an internship and residency in clinical pathology at the U.S. Public Health Service Hospital in Baltimore, a residency in anatomic pathology at the University of Maryland Hospital, and as a staff physician with the U.S. Public Health Service Outpatient Clinic in Miami, Florida. He was assistant chief of pathology at the U.S. Public Health Service Hospital in Baltimore, and prior to joining the staff at St. Agnes Hospital, served as associate pathologist at Mercy Hospital.

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Medical Miscellany

AMA's Survey and Opinion Briefs

Physicians' Preferences for Payment Methods

At the 1983 Interim Meeting of the House of Delegates in Los Angeles, the American Medical Association recognized "the validity of a pluralistic approach to third party reimbursement methodology and that indemnity reimbursement as a schedule of benefits, as well as 'usual and customary or reasonable' (UCR), have positive aspects which merit further indepth study."

As part of this ongoing effort to study physician reimbursement, a question was included on the AMA's physician opinion poll to measure preferences for various methods of payment. Because this is a new question, these findings should be regarded as preliminary and interpreted cautiously. Data were collected in August 1983 via telephone interviews with 1,000 randomly selected physicians.

Survey Data

There has been a lot of discussion about different kinds of health insurance plans and how they reimburse physicians.

***Indemnity plans** pay a fixed price for procedures, and the physician then negotiates directly with the patient over any additional charge.*

***UCR plans** reimburse on the basis of complex and varied formulas and patients are billed for any remaining charges.*

***Prepaid or HMO plans** usually reimburse physicians on a salary and incentive basis.*

Of these three—the indemnity, UCR, or prepaid plan—which do you prefer?

	Percent
Indemnity	34
UCR	29
Prepaid	18
Unsure	19

The results were quite surprising in several respects. While indemnity receives a slight edge, the dispersion of responses is striking. Only one in three physicians prefers UCR reimbursement, and fully 18 percent of physicians interviewed indicate preference for a salary plus incentive method of payment. *However, almost one in five physicians are unsure of their views on this important issue.* It is also very clear that no one method is dominant as indemnity and UCR together only account for about six in ten responses. Examining preferences by age and AMA membership status reveals further differences.

Preference	Age		Membership	
	Under 45	45+	Member	Nonmember
Indemnity	31	37	36	32
UCR	35	21	35	23
Prepaid	19	17	12	24
Unsure	15	25	18	21

Boxes are drawn around the key comparisons. As indicated, younger physicians are significantly more likely to prefer UCR than their older colleagues. In contrast, older physicians are more likely to be unsure about their preference, perhaps as a result of negative experiences with each alternative. On the membership side, members are much more likely to prefer UCR than nonmembers, although even among AMA members indemnity is still most preferred. Finally, nonmembers are twice as likely as members to prefer the prepaid salary plus incentive option.

While there is some overlap between the two variables (nonmembers tend to be young), their effects on these preferences are somewhat additive. For example, 46 percent of young members prefer UCR; only 15 percent of older nonmembers do so. Young members is the only group in which preferences for UCR outweigh those for indemnity plans.

Discussion

These survey findings mesh very well with the House of Delegates' call for "a pluralistic approach to third-party reimbursement." Physicians' preferences for payment methods are dispersed widely among indemnity, UCR, and prepaid salary options, and fully 19 percent of physicians are unsure of where they stand on this rapidly changing issue.

It is somewhat surprising that indemnity emerges as the most preferred method. It will be very interesting to track these preferences over time. The strong support for UCR among younger as compared to older physicians is also somewhat unexpected and will be watched with interest.

Not so unexpected is the substantial negative relationship between membership and preference for the prepaid salary plus incentive option. Physician opinion toward the prepaid group practice type of organization has been related to membership in past studies, and the link is reconfirmed here. Because of its growing importance, the issue of physician payment methods will be given much greater attention in the AMA's surveys.

Whatever the method of third party reimbursement, disputes between physicians and patients over charges will continue unless fees are discussed fully in advance of services. The AMA's 1983 public opinion survey

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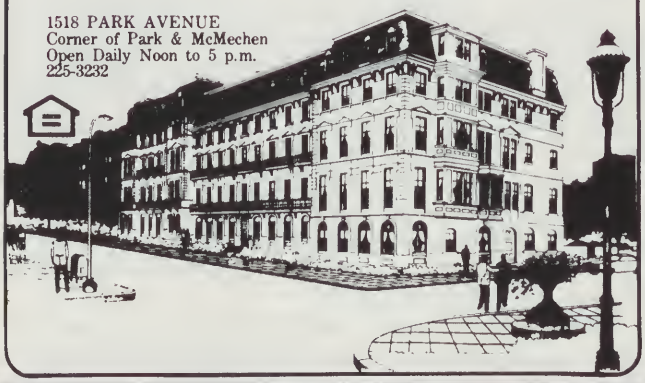
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asked, "Do you discuss fees ahead of time with your doctor?" Of those who reported having a family physician, only 20 percent responded Yes. Until this percentage increases dramatically, problems with all types of reimbursement will continue.

If you have comments or questions regarding this information, contact Larry Freshnock, Director, Survey and Opinion Research (312-645-4450).

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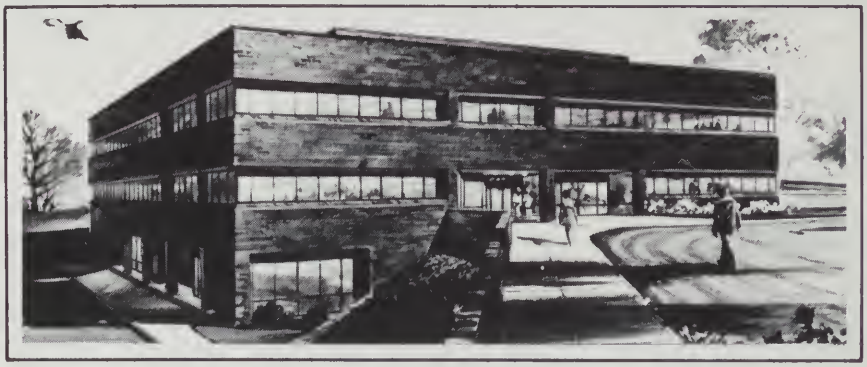
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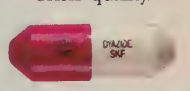
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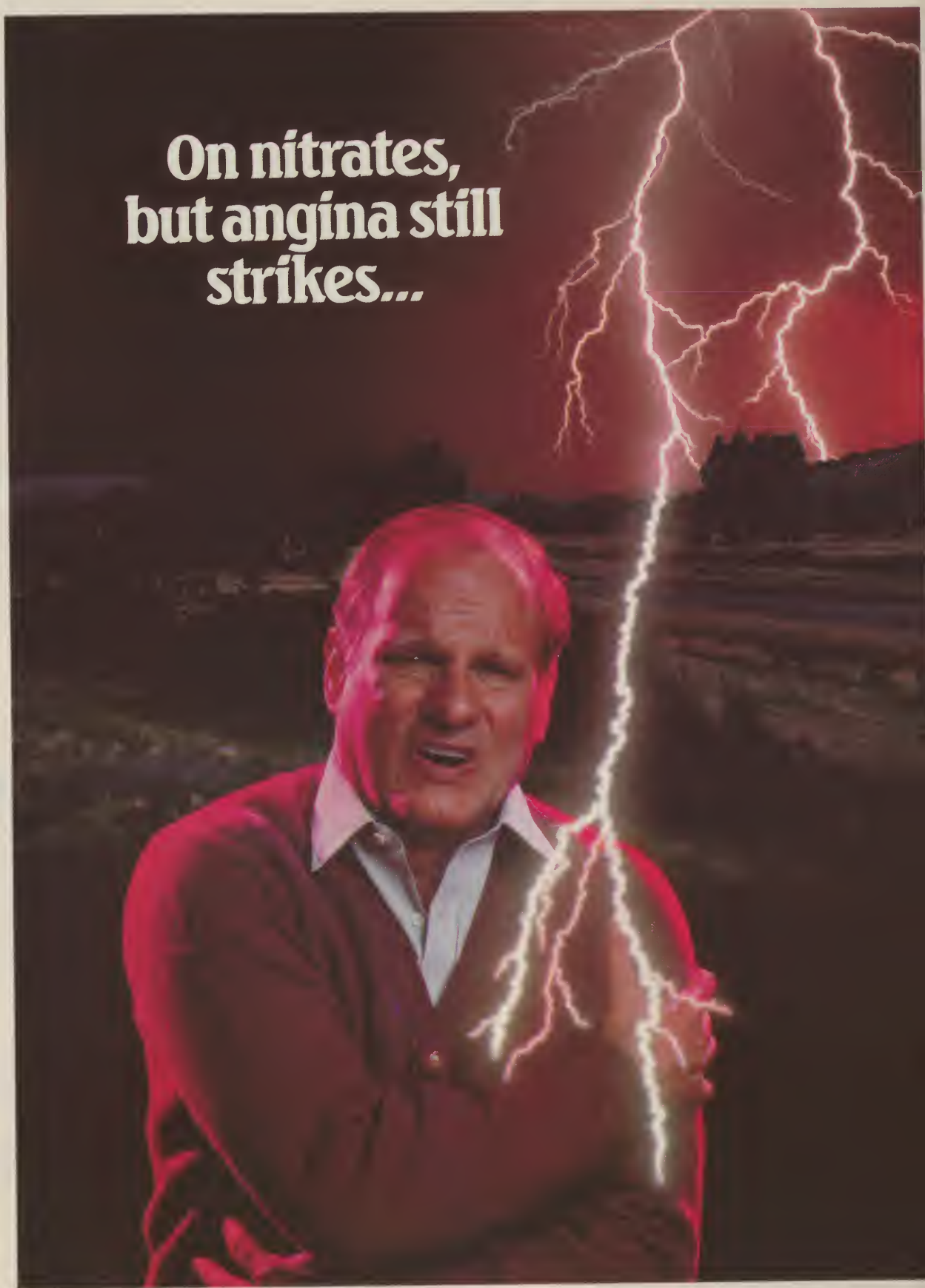
Thiazides may add to or potentiate the action of other antihypertensive drugs.

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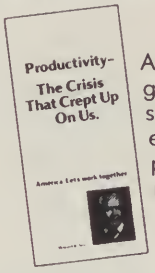
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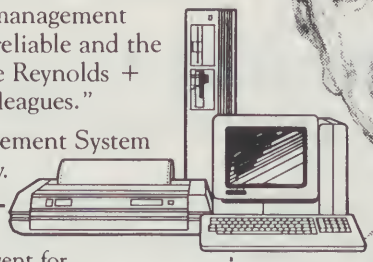
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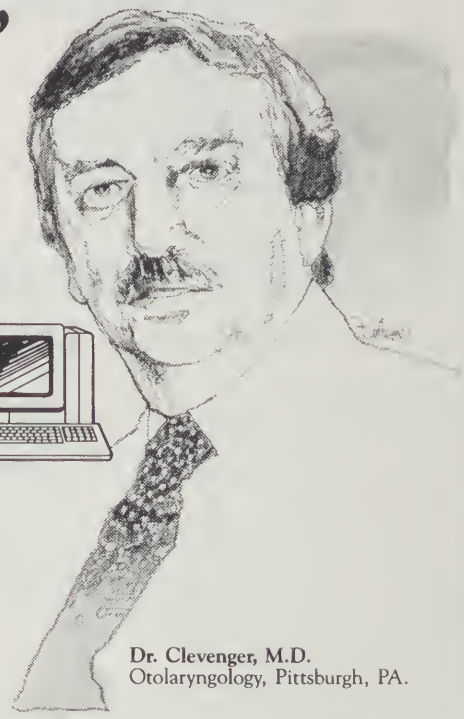
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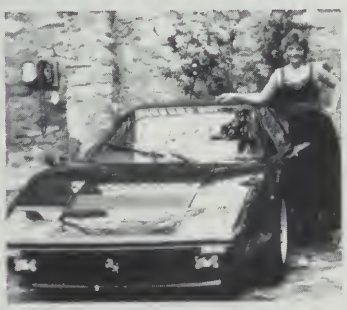
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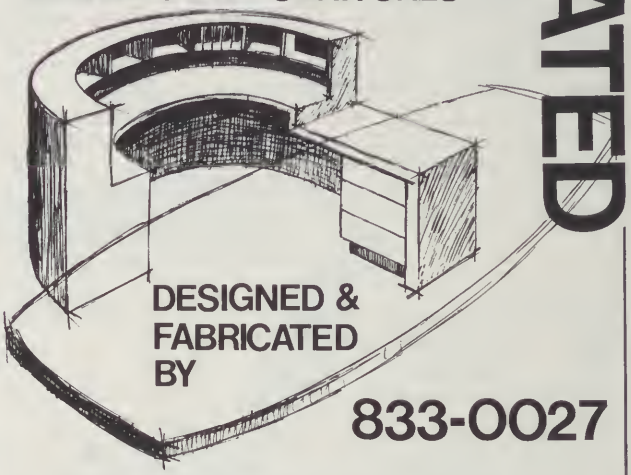
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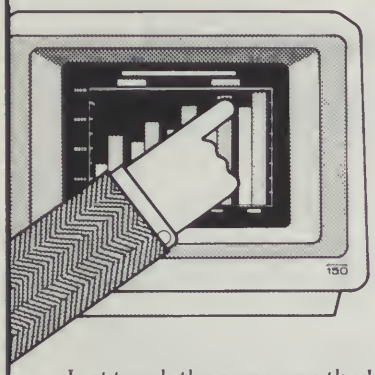
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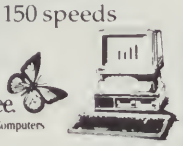
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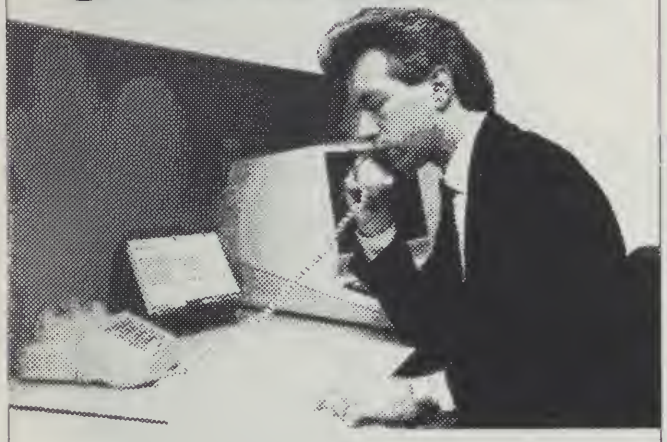
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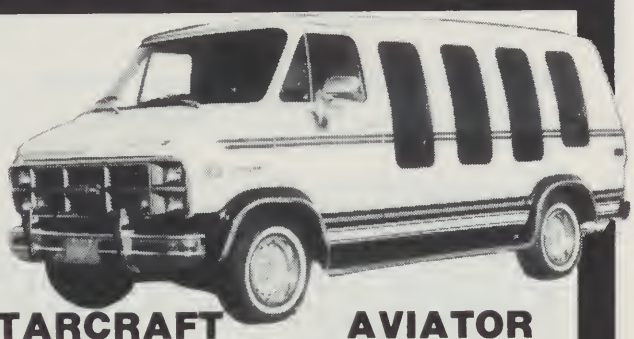
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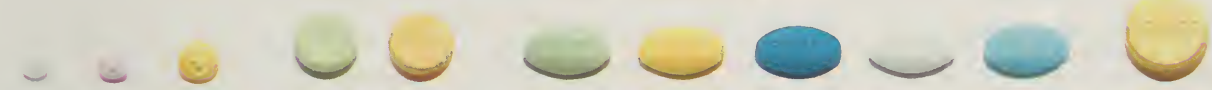


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See following page for brief summary of prescribing information.

SORBITRATE®
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Please consult full prescribing information before use. A summary follows:

INDICATIONS AND USAGE: SORBITRATE (isosorbide dinitrate) is indicated for the treatment and prevention of angina pectoris. All dosage forms of isosorbide dinitrate may be used prophylactically to decrease frequency and severity of anginal attacks and can be expected to decrease the need for sublingual nitroglycerin.

The sublingual and chewable forms of the drug are indicated for acute prophylaxis of angina pectoris when taken a few minutes before situations likely to provoke anginal attacks. Because of a slower onset of effect, the oral forms of isosorbide dinitrate are not indicated for acute prophylaxis.

CONTRAINDICATIONS: SORBITRATE is contraindicated in patients who have shown purported hypersensitivity or idiosyncrasy to it or other nitrates or nitrites. Epinephrine and related compounds are ineffective in reversing the severe hypotensive events associated with overdose and are contraindicated in this situation.

WARNINGS: The benefits of SORBITRATE during the early days of an acute myocardial infarction have not been established. If one elects to use organic nitrates in early infarction, hemodynamic monitoring and frequent clinical assessment should be used because of the potential deleterious effects of hypotension.

PRECAUTIONS: General: Severe hypotensive response, particularly with upright posture, may occur with even small doses of SORBITRATE. The drug should therefore be used with caution in subjects who may have blood volume depletion from diuretic therapy or in subjects who have low systolic blood pressure (eg, below 90 mmHg). Paradoxical bradycardia and increased angina pectoris may accompany nitrate-induced hypotension. Nitrate therapy may aggravate the angina caused by hypertrophic cardiomyopathy.

Marked symptomatic, orthostatic hypotension has been reported when calcium channel blockers and organic nitrates were used in combination. Dose adjustment of either class of agents may be necessary.

Tolerance to this drug and cross-tolerance to other nitrates and nitrites may occur. Tolerance to the vascular and antianginal effects of isosorbide dinitrate or nitroglycerin has been demonstrated in clinical trials, experience through occupational exposure, and in isolated tissue experiments in the laboratory. The importance of tolerance to the appropriate use of isosorbide dinitrate in the management of patients with angina pectoris has not been determined. However, one clinical trial using treadmill exercise tolerance (as an end point) found an 8-hour duration of action of oral isosorbide dinitrate following the first dose (after a 2-week placebo washout) and only a 2-hour duration of effect of the same dose after 1 week of repetitive dosing at conventional dosing intervals. On the other hand, several trials have been able to differentiate isosorbide dinitrate from placebo after 4 weeks of therapy and, in open trials, an effect seems detectable for as long as several months.

Tolerance clearly occurs in industrial workers continuously exposed to nitroglycerin. Moreover, physical dependence also occurs since chest pain, acute myocardial infarction, and even sudden death have occurred during temporary withdrawal of nitroglycerin from the workers. In clinical trials in angina patients, there are reports of anginal attacks being more easily provoked and of rebound in the hemodynamic effects soon after nitrate withdrawal. The relative importance of these observations to the routine, clinical use of isosorbide dinitrate is not known. However, it seems prudent to gradually withdraw patients from isosorbide dinitrate when the therapy is being terminated, rather than stopping the drug abruptly.

Information for Patients: Headache may occur during initial therapy with SORBITRATE. Headache is usually relieved by the use of standard headache remedies or by lowering the dose and tends to disappear after the first week or two of use.

Drug Interactions: Alcohol may enhance any marked sensitivity to the hypotensive effect of nitrates.

Isosorbide dinitrate acts directly on vascular smooth muscle; therefore, any other agent that depends on vascular smooth muscle as the final common path can be expected to have decreased or increased effect depending on the agent.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term studies in animals have been performed to evaluate the carcinogenic potential of this drug. A modified two-litter reproduction study in rats fed isosorbide dinitrate at 25 or 100 mg/kg/day did not reveal any effects on fertility or gestation or any remarkable gross pathology in any parent or offspring fed isosorbide dinitrate as compared with rats fed a basal-controlled diet.

Pregnancy Category C: Isosorbide dinitrate has been shown to cause a dose-related increase in embryotoxicity (increase in mummified pups) in rabbits at oral doses 35 and 150 times the maximum recommended human daily dose. There are no adequate and well-controlled studies in pregnant women. SORBITRATE should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when SORBITRATE is administered to a nursing woman.

Pediatric Use: The safety and effectiveness of SORBITRATE in children has not been established.

ADVERSE REACTIONS: Adverse reactions, particularly headache and hypotension, are dose-related. In clinical trials at various doses, the following have been observed:

Headache is the most common (reported incidence varies widely, apparently being dose-related, with an average occurrence of about 25%) adverse reaction and may be severe and persistent. Cutaneous vasodilation with flushing may occur. Transient episodes of dizziness and weakness, as well as other signs of cerebral ischemia associated with postural hypotension, may occasionally develop (the incidence of reported symptomatic hypotension ranges from 2% to 36%). An occasional individual will exhibit marked sensitivity to the hypotensive effects of nitrates and severe responses (nausea, vomiting, weakness, restlessness, pallor, perspiration, and collapse) may occur even with the usual therapeutic dose. Drug rash and/or exfoliative dermatitis may occasionally occur. Nausea and vomiting appear to be uncommon. Case reports of clinically significant methemoglobinemia are rare at conventional doses of organic nitrates. The formation of methemoglobin is dose-related and, in the case of genetic abnormalities of hemoglobin that favor methemoglobin formation, even conventional doses of organic nitrate could produce harmful concentrations of methemoglobin.

DOSAGE AND ADMINISTRATION: For the treatment of angina pectoris, the usual starting dose for sublingual SORBITRATE is 2.5 to 5 mg; for chewable tablets, 5 mg; for oral (swallowed) tablets, 5 to 20 mg, and for controlled-release forms, 40 mg.

SORBITRATE should be titrated upward until angina is relieved or side effects limit the dose. In ambulatory patients, the magnitude of the incremental dose increase should be guided by measurements of standing blood pressure.

The initial dosage of sublingual or chewable SORBITRATE for prophylactic therapy in angina pectoris patients is generally 5 or 10 mg every 2 to 3 hours. Adequate controlled clinical studies demonstrating the effectiveness of chronic maintenance therapy with these dosage forms have not been reported.

SORBITRATE in oral doses of 10 to 40 mg given every 6 hours or in oral controlled-release doses of 40 to 80 mg given every 8 to 12 hours is generally recommended. The extent to which development of tolerance should modify the dosage program has not been defined. *The oral controlled-release forms of isosorbide dinitrate should not be chewed.*

DOSAGE FORMS AVAILABLE: Sublingual Tablets (2.5, 5, 10 mg); Chewable Tablets (5, 10 mg); Oral Tablets (5, 10, 20, 30, 40 mg); Sustained Action Tablets (40 mg).

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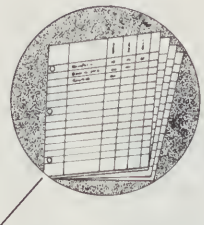
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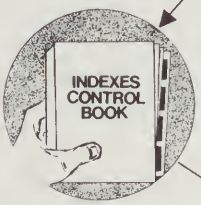
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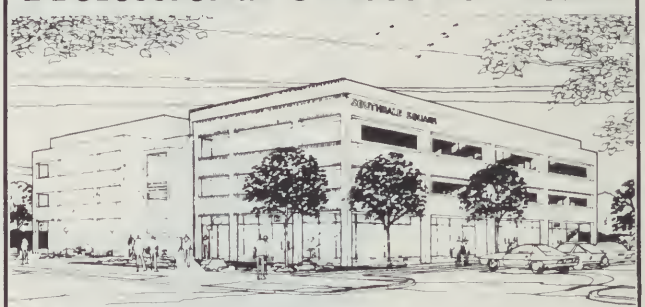
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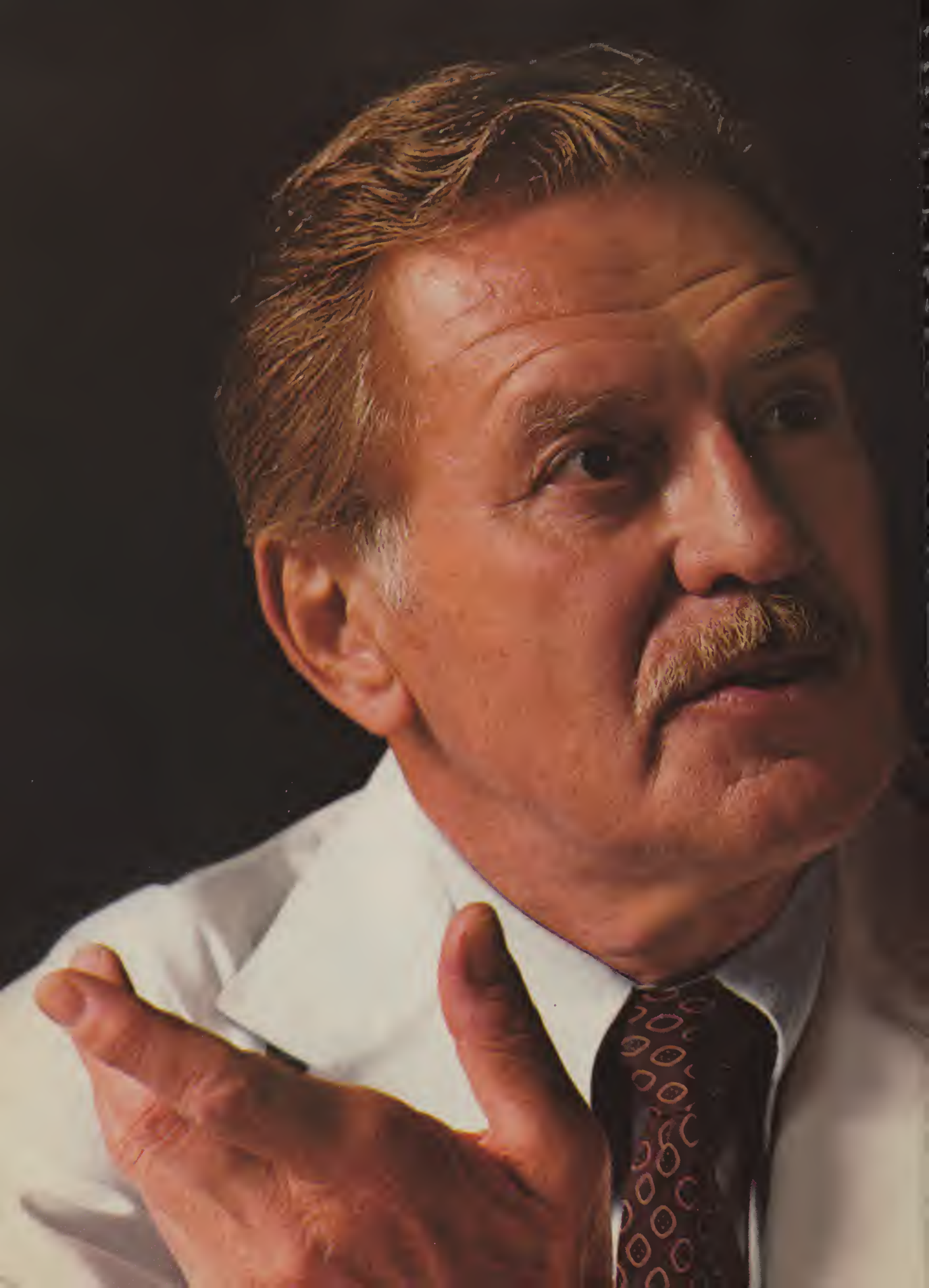
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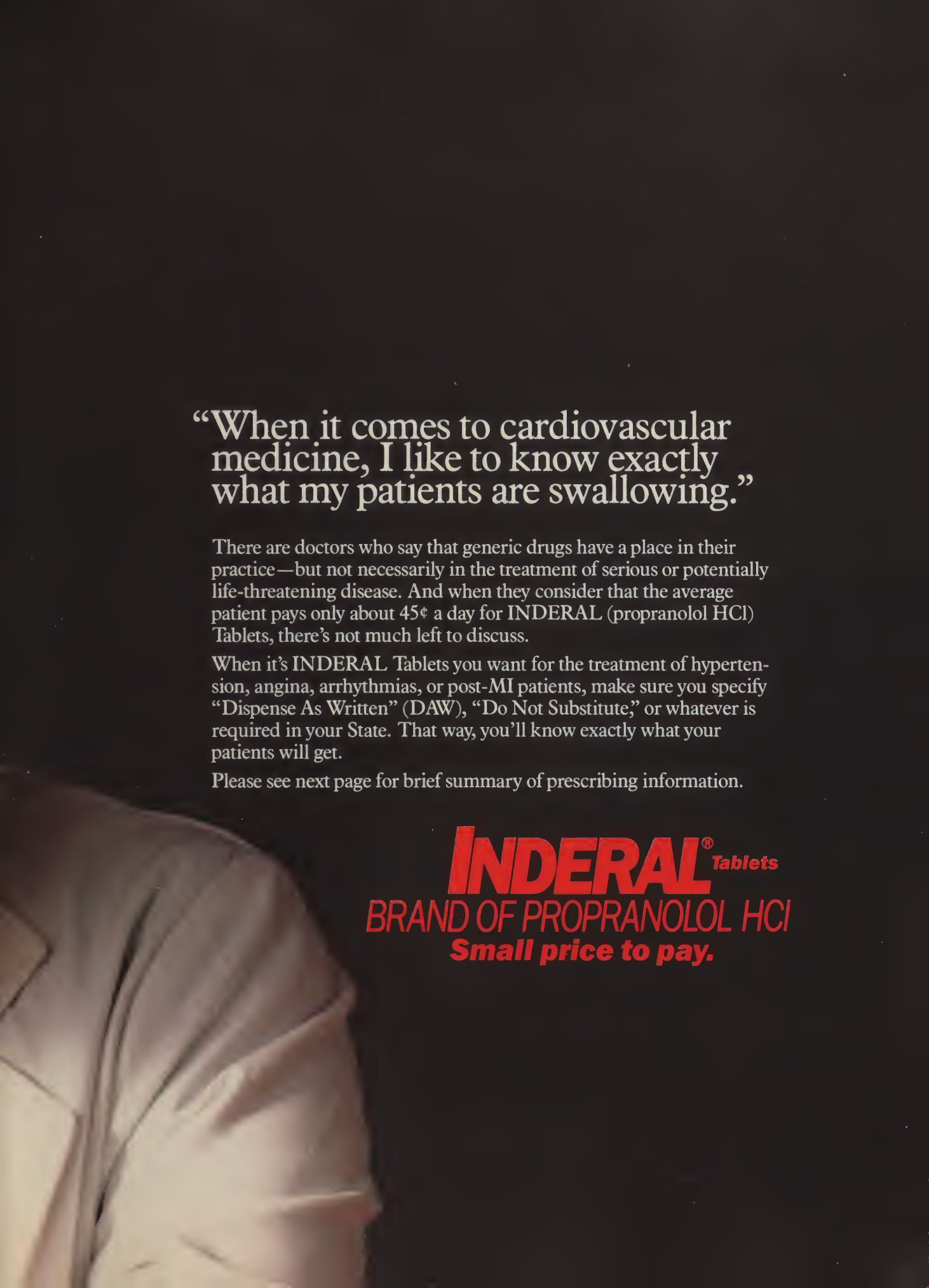
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J-4044 January 1984




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CONTRAINDICATIONS

INDERAL is contraindicated in 1) cardiogenic shock, 2) sinus bradycardia and greater than first degree block, 3) bronchial asthma, 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with INDERAL.

WARNINGS

CARDIAC FAILURE: Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or INDERAL should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of INDERAL therapy. Therefore, when discontinuance of INDERAL is planned the dosage should be gradually reduced over at least a few weeks and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If INDERAL therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute INDERAL therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema)—PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. INDERAL should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY: The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

INDERAL, like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, e.g., dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOGLYCEMIA: Beta-adrenergic blockade may prevent the appearance of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more difficult to adjust the dosage of insulin.

THYROTOXICOSIS: Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol does not distort thyroid function tests.

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS

General: Propranolol should be used with caution in patients with impaired hepatic or renal function. INDERAL is not indicated for the treatment of hypertensive emergencies.

Beta-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should be told that INDERAL (propranolol hydrochloride) may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

Clinical Laboratory Tests: Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase

DRUG INTERACTIONS: Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if INDERAL is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

Pregnancy: Pregnancy Category C. INDERAL has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose

There are no adequate and well-controlled studies in pregnant women. INDERAL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus

Nursing Mothers: INDERAL is excreted in human milk. Caution should be exercised when INDERAL is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established

ADVERSE REACTIONS

Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: bradycardia; congestive heart failure, intensification of AV block; hypotension; paresthesia of hands; thrombocytopenic purpura; arterial insufficiency, usually of the Raynaud type.

Central Nervous System: Lightheadedness; mental depression manifested by insomnia, lassitude, weakness, fatigue; reversible mental depression progressing to catatonia; visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Gastrointestinal: nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress

Respiratory: bronchospasm.

Hematologic: agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-Immune: In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: alopecia, LE-like reactions, psoriasiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

*The appearance of INDERAL tablets is a registered trademark of Ayerst Laboratories.

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Doctors Take Note

University of Maryland School of Medicine

CME Courses: For each course additional information may be obtained by contacting Program of Continuing Education, University of Maryland School of Medicine, Room 300, MSTF, 10 South Pine St., Baltimore, MD 21201 (301-528-3956).

Apr 18–May 14 Advanced Immunology. Info: 301-528-7110.

May 3–4 Contemporary Issues in the Diagnosis and Management of Chronic Congestive Heart Failure. Baltimore. Fee: $170; 10 AMA Cat I credits.

June 17–18 Symposium on Perinatal Endocrinology. Baltimore. Fee: $150; 14 AMA Cat I credits and 14 ACOG cognates.

June 23–28 Eleventh Annual Family Medicine Review Course, Ocean City. Fee: $350.

June 27–29 Dermatology Days, Ocean City. Early fee: $230; 11.25 AMA Cat I credits.

Oct thru May—Visiting Practitioner Preceptorship Program. CME experience on full-time clinical basis in choice of discipline; 5 days to 6 weeks. Hour-to-hour AMA Cat I credits.

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Miscellaneous Meetings

Apr 19–21 Emergency Medicine for the Primary Care Physician, sponsored by the Office of Continuing Medical Education, the Medical College of Virginia. Fee: $250; 16.5 instruction hours. Info: K. Martin (808-786-0494).

Apr 22–24 NIH Consensus Development Conference: Anesthesia and Sedation in the Dental Office. NIH Clinical Center, Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Info: P. Murphy, Prospect Associates, Suite 401, 2115 E. Jefferson St., Rockville, MD 20852 (301-468-6555).

Apr 24 First Annual Symposium: Inflammatory Bowel Disease for Primary Care Physicians, The Fairfax Hospital, Falls Church, VA 22046. Info: 703-698-3101.

Apr 25–28 Annual Meeting, The Virginia Society of Otolaryngolog-Head and Neck Surgery, Tides Inn, Irvington, VA. Info: D. Strawderman, 4205 Dover Rd., Richmond VA 23221 (804-353-2721).

May 8 Disability and the Social Security Administration. CME topic of the American Medical Women's Association. Meeting held at the Johns Hopkins Faculty Club, Homewood Campus; cash bar at 6:30 p.m.; dinner at 7 p.m.

May 8–10 Clinical Applications of Doppler Echocardiography—1985, at the American College of Cardiology's Learning Center in Bethesda. Fee: $375, members; $435, nonmembers; 21 Cat I ACCME credits. Info: ACC Learning Center Registrar, 9111 Old Georgetown Rd., Bethesda, MD 20814 (301-897-5400, ext. 241).

May 8–11 Annual Meeting, The Virginia Society of Ophthalmology, Boar's Head Inn, Charlottesville, VA. Cosponsored by University of Virginia Ophthalmology Dept. Info: D. Strawderman, 4205 Dover Rd., Richmond, VA 23221 (804-353-2721).

May 8–12 Annual Meeting and Scientific Session of the Maryland Academy of Family Physicians, Ocean City. Fee: $100 (members), $150 (nonmembers). Info: J. Zebley MD, Program Chairman (301-659-0640).

May 9 The Challenge of Hypertension Compliance: How to Increase Patient Adherence, presented by the Center for Health Education, Inc. at Bon Secours Hospital. 11 a.m.–1 p.m. (lunch); 2 AMA Cat I credits, 2 prescribed hours AAFP. Info: J. Mannion 301-837-2705.

May 14 The Challenge of Hypertension Compliance: How to Increase Patient Adherence, presented by the Center for Health Education, Inc. at Church Hospital. 5 p.m.–7 p.m. (snacks); 2 AMA Cat I credits, 2 prescribed hours AAFP. Info: J. Mannion 301-837-2705.

May 15–17 Update in Infectious Diseases, Philadelphia. Info: Registrar, American College of Physicians, 4200 Pine St., Philadelphia, PA 19104.

May 20–22 Clinical Applications of Stress Testing Techniques in Coronary Heart Disease, American College of Cardiology's Learning Center in Bethesda. Fee: $375, members; $435, nonmembers; 16.5 Cat I credits. Info: ACC Learning Center Registrar, 9111 Old Georgetown Rd., Bethesda, MD 20814 (301-897-5400, ext. 241).

May 22 The Challenge of Hypertension Compliance: How to Increase Patient Adherence, presented by the Center for Health Education, Inc. at North Charles General Hospital. 5 p.m.–7 p.m. (snacks); 2 AMA Cat I credits, 2 prescribed hours AAFP. Info: J. Mannion 301-837-2705.

Jun 5–7 Current Concepts in Oncology and Hematologic Malignancies, Philadelphia. Info: Registrar, American College of Physicians, 4200 Pine St., Philadelphia, PA 19104.

Jun 10–12 Consensus Development Conference on Electroconvulsive Therapy. NIH Clinical Center, Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Info: M. Dillon, Prospect Associates, Suite 401, 2115 East Jefferson St., Rockville, MD 20852 (301-468-6555).

Jun 16–21 Eighth Annual Eastern Shore Medical Symposium, Rehoboth Beach, DE. Sponsored by Jefferson Medical College, The Medical Society of Delaware, University of Delaware. 29 AMA Cat I credits. Info: S. Brocka, University of Delaware, Wilcastle Center, 2800 Pennsylvania Ave., Wilmington, DE 19806 (302-573-4400).

Aug 4–9 An Intensive Review of Internal Medicine, Jefferson Medical College in cooperation with the University of Delaware. 45 Cat I AMA credits. Info: S. Brocka, University of Delaware, 2800 Pennsylvania Ave., Wilmington, DE 19806 (302-573-4400).

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Taylor Manor Hospital CME Lectures

All lectures at 3 p.m. in the Psychiatric Center at Taylor Manor Hospital, Ellicott City, MD unless otherwise indicated. Info: Taylor Manor Hospital, College Ave., Ellicott City, MD 21043 (301-465-3322).

Jun 12 Self-Mutilation in the Young.

• • •

The Johns Hopkins Medical Institution

All courses at the Turner Auditorium Building unless otherwise indicated. Sponsored Continued Education Activities for 1984–85. Info: Office of Continuing Education, 720 Rutland Ave., Turner Auditorium, Baltimore, MD 21205 (301-955-5880).

Apr 20 Current Concepts in Thyroid Disease. Fee: $90; 9 AMA Cat I credits. Info: D. Heydinger (301-955-6046).

May 13–16 Advances and Controversies in Emergency Medicine. Fee: physicians, 4 days/$395, 1 day/$145; physicians-in-training, 4 days/$215, 1 day/$100. 25 hours of instruction. Info: J. Ryan (301-955-6046).

May 17 Photocoagulation for the Neovascular Maculopathies. Fee: residents, $160; fellows, $80; 8 Cat I AMA credits. Info: A. Kearney (301-955-6046).

May 14–16 Epidemiology and Health Risk Assessment, sponsored by the Johns Hopkins University School of Hygiene and Public Health, Dept. of Epidemiology. Fee: $130; 20 AMA Cat I credits, CEU. Info: C. Kearney (301-955-3168).

Jun 6–7 Cancer and Nutrition: A 1985 Update on Chemoprevention Trials and Therapeutic Management. Info: A. Kearney (301-955-6046).

Continuously throughout the year: One-week Microsurgery Training Course, Basic techniques and principles, individualized instruction, and practice sessions. Fee: $1,200; 40 AMA Cat I credits. Info: Prog. Coord. (301-955-3169).

The Department of Radiology and Radiological Science, offers several courses in abdominal and obstetrical ultrasound: courses scheduled Jan 14 to Dec 6, 1985. Info: Joan Mosmiller, Department of Radiology (301-955-8450).

Basic Practicum—June 3–7; Aug 5–9; Sep 23–27. Fee: $460; 40 AMA Cat I credits.

Advanced Practicum—May 13–17; Dec 2–6. Fee $460; 40 AMA Cat I credits.

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Diagnostic Ultrasound in Obstetrics and Gynecology course given annually attracts world's leading experts in the field of obstetrical and gynecology ultrasound. Sep 12–13, 1985; 16 AMA Cat I credits.

The Johns Hopkins Medical Grand Rounds. Accredited audiovisual subscription program for the practicing physician. 40 AMA Cat I credits/year. Write to the Johns Hopkins University School of Medicine, Office of Continuing Education, 720 Rutland Ave., Baltimore, MD 21205 (301-955-3988).

Clinical Cytopathology for Pathologists, 1985 Postgraduate Institute: March to May 1985, Home Study Course A; **May 6–17,** In-Residence Course B at the Johns Hopkins Medical Institution, Baltimore. Special arrangements to study Course A must be made by participants outside the U.S. and Canada. 152 AMA Cat I credits. *The entire course given in English.*

Completed preregistration must be accomplished before **April 5, 1985,** unless by special arrangement. Info: John K. Frost, MD, 604 Pathology Bldg., The Johns Hopkins Hospital, Baltimore, MD 21205, USA.

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The Medical and Chirurgical Faculty of the State of Maryland maintains a Placement Service for the convenience of Maryland physicians, hospitals and communities in search of candidates for positions available in our state. A detailed description of such opportunities should be forwarded to the Physician Placement Service, 1211 Cathedral St., Baltimore, MD 21201; telephone 1-301-539-0872.

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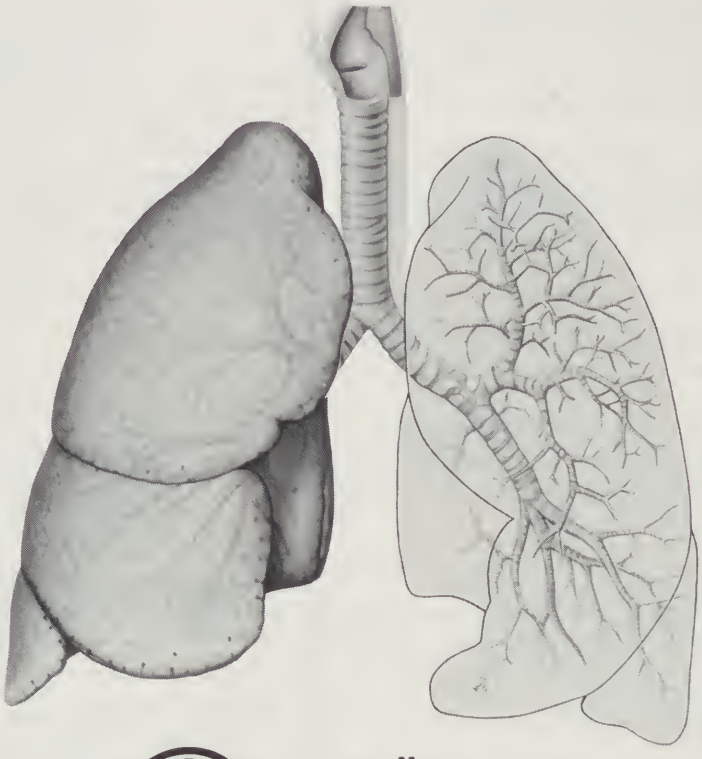
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Brief Summary. Consult the package literature for prescribing information.

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Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae), Haemophilus influenzae,* and *S. pyogenes* (group A beta-hemolytic streptococci).

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor.

Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

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Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile.* Other causes of colitis should be ruled out.

Precautions: *General Precautions* — If an allergic reaction to Ceclor* (cefaclor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest* tablets but not with Tes-Tape* (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy — *Pregnancy Category B* — Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor* (cefaclor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers — Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Ceclor is administered to a nursing woman.

Usage in Children — Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below.

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbilliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic — Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic — Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal — Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[061782R]

Note: Ceclor* (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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Advertisers' Index

Rafael Alfonso MD, PA 410
Allstate Leasing Inc. 316
AMA 399
American Lung Association 396
American Office 369
Associated Speech & Language Services 402
BTR Realty Inc. 398
Beethoven/Rielh Estate Management 378
Blue Shield of Maryland 312
Bon Secours Professional Center 324
Business Automation Inc. 390
Campbell Laboratories 323
Cellular One 394
Commercial Brokerage Group, Inc. 398
Consultative Examinations, Inc. 410
Crawford Door Sales of Maryland 390
Creative Health Seminar Consultants 402
Curtis 1000 315
Diagnostic Assay Services, Inc. 313
Elkridge Estates 361
Emergency Medical Group 411
Family Home Care 413
Family Recovery Center 413
John M. T. Finney III Realtor® 398
Freestate Management Co. 382
GMC Truck Center 391
Gordon & Heneson P.A. 392
Heron Harbour Isle 327
Hidden Brook Treatment Center 321
Intracare Corp. 379
JBA Leasing 388
Jerry's Toyota 322
King's Grant 310
Knoll Pharmaceutical 383
Joel R. Kruh Esq. 410
Lewis Medical Instruments 314
Eli Lilly & Co. 412
MISC 316
Marion Laboratories 363
Maryland Army National Guard 410
Maryland Office Systems 391
Maryland Medical Laboratory, Inc. 309
Med-Chi 373, 388, 392
Medical Mutual Liability ..... cover 2, 380
Michaelson Motors, Inc. 378
Micro Computer 388
Miller Studio 361
Mountain Manor Treatment Center 371
Multicom Inc. 397
McGrow, Pridgeon & Co. PA 350
National Credit Management Corp. 391
Nurses, Inc. 402
Oakview Treatment Center 389
Old Court Nursing Center 382
Parke-Davis 365
Personal Organization, Inc. 398
PM Baltimore 362
Postgraduate Medicine 323
RJL Leasing 389
Roche Laboratories ..... cover 3 & 4
St. Agnes Hospital 411
W. James Schiller & Co. PA 391
Schumacher & Seiler, Inc. 393
Sheppard & Enoch Pratt Hosp. 358
Sheraton Inner Harbor Hotel 401
E. R. Squibb 317, 343
Staff Builders 389
Stuart Pharmaceutical 395
Sunspace Design Studio 390
Tekmatix 411
Towson Valley Motors 414
Uncle Lee's Restaurant 389
USAF Recruiting 362
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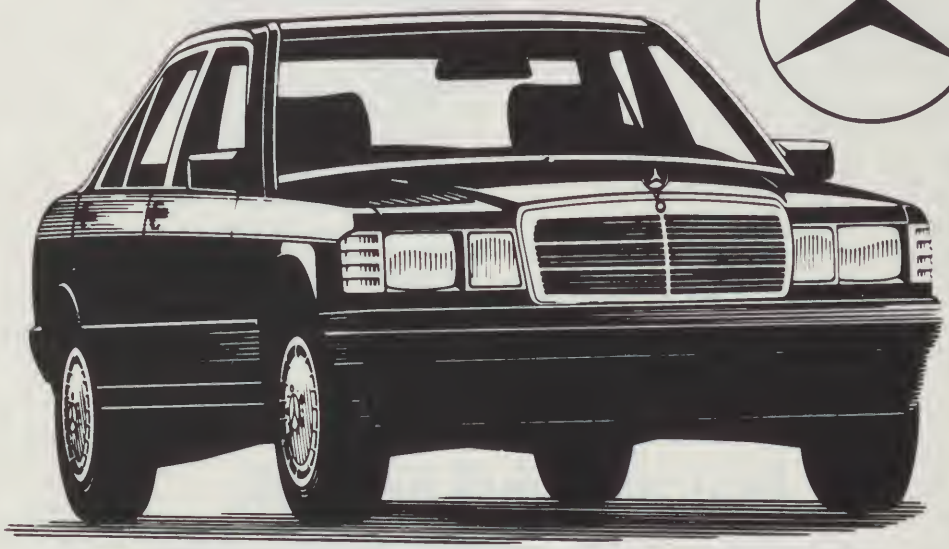
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Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants. An additive effect may occur if alcohol is consumed the day following use for nighttime sedation. This potential may exist for several days following discontinuation. Caution against hazardous occupations requiring complete mental alertness (*e.g.*, operating machinery, driving). Potential impairment of performance of such activities may occur the day following ingestion. Not recommended for use in persons under 15 years of age. Though physical and psychological dependence have not been reported on recommended doses, abrupt discontinuation should be avoided with gradual tapering of dosage for those patients on medication for a prolonged period of time. Use caution in administering to addiction-prone individuals or those who might increase dosage.

Precautions: In elderly and debilitated patients, it is recommended that the dosage be limited to 15 mg to reduce risk of oversedation, dizziness, confusion and/or ataxia. Consider potential additive effects with other hypnotics or CNS depressants. Employ usual precautions in severely depressed patients, or in those with latent depression or suicidal tendencies, or in those with impaired renal or hepatic function.

Adverse Reactions: Dizziness, drowsiness, lightheadedness, staggering, ataxia and falling have occurred, particularly in elderly or debilitated patients. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported: headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, GI pain, nervousness, talkativeness, apprehension, irritability, weakness, palpitations, chest pains, body and joint pains and GU complaints. There have also been rare occurrences of leukopenia, granulocytopenia, sweating, flushes, difficulty in focusing, blurred vision, burning eyes, faintness, hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anorexia, euphoria, depression, slurred speech, confusion, restlessness, hallucinations, and elevated SGOT, SGPT, total and direct bilirubins, and alkaline phosphatase; and paradoxical reactions, *e.g.*, excitement, stimulation and hyperactivity.

Dosage: Individualize for maximum beneficial effect. *Adults:* 30 mg usual dosage; 15 mg may suffice in some patients. *Elderly or debilitated patients:* 15 mg recommended initially until response is determined.

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Executive Director's Newsletter 431
Hotline Numbers 439, 459, 519
Medicolegal Hotline 440
Physicians' Placement Service 442
Medical Miscellany 457
Members in the News 460
Consultation 497
Information for Authors 498
Change of Address Form 499
Doctors Take Note 518
Classified Ads 521
Advertisers' Index 523

ARTICLES

Osteoarthritis VIII: Surgical Management of the Knee—Dennis W. Lennox MD 463

Preventive Cardiology—Karen Kuehl MD 473

The Newborn with Acyanotic Congenital Heart Disease: Recognition and Management—Lowell W. Perry MD 477

Chest Pain in Children: Identifying a Source—Joel I. Brenner MD, Richard E. Ringel MD, and Michael A. Berman MD 481

Noninvasive Assessment of Pediatric Congenital Heart Disease—Lowell W. Perry MD 493

Aftermath of Pediatric Heart Surgery—Langford Kidd MD 499

Child Abuse and Neglect: Sexual Abuse of Prepubertal Children—Charles I. Shubin MD 503

DEPARTMENTS

Inside Med-Chi 436

Your Medical Faculty at Work 437

The Library Page 438

Baltimore Country Medical Association 440

One Minute with Diabetes 440

Maryland Oncology Newsletter 442

Disease Control and Epidemiology Newsletter 444

HBP Commentary 455

Semiannual Meeting Announcement 456

Auxiliary 459

Commission on Medical Discipline: Dual Fee Schedule Opinion 461

Discipline Commission Action 514

Pediatric cardiology was the theme of a recent symposium sponsored by the Maryland Chapter of the American Academy of Pediatrics. Subjects of importance to physicians caring for infants and children with heart disease were addressed by speakers from the Children's Hospital National Medical Center, the Johns Hopkins Children's Medical Center, and the University of Maryland. We are pleased to present these lectures as articles beginning on page 473.

Cover illustration: Elizabeth W. McDonnell, Scientific Illustration Division, Armed Forces Institute of Pathology.

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The sublingual and chewable forms of the drug are indicated for acute prophylaxis of angina pectoris when taken a few minutes before situations likely to provoke anginal attacks. Because of a slower onset of effect, the oral forms of isosorbide dinitrate are not indicated for acute prophylaxis.

CONTRAINDICATIONS: SORBITRATE is contraindicated in patients who have shown purported hypersensitivity or idiosyncrasy to it or other nitrates or nitrites. Epinephrine and related compounds are ineffective in reversing the severe hypotensive events associated with overdose and are contraindicated in this situation.

WARNINGS: The benefits of SORBITRATE during the early days of an acute myocardial infarction have not been established. If one elects to use organic nitrates in early infarction, hemodynamic monitoring and frequent clinical assessment should be used because of the potential deleterious effects of hypotension.

PRECAUTIONS: General: Severe hypotensive response, particularly with upright posture, may occur with even small doses of SORBITRATE. The drug should therefore be used with caution in subjects who may have blood volume depletion from diuretic therapy or in subjects who have low systolic blood pressure (eg, below 90 mmHg). Paradoxical bradycardia and increased angina pectoris may accompany nitrate-induced hypotension. Nitrate therapy may aggravate the angina caused by hypertrophic cardiomyopathy.

Marked symptomatic, orthostatic hypotension has been reported when calcium channel blockers and organic nitrates were used in combination. Dose adjustment of either class of agents may be necessary.

Tolerance to this drug and cross-tolerance to other nitrates and nitrites may occur. Tolerance to the vascular and antianginal effects of isosorbide dinitrate or nitroglycerin has been demonstrated in clinical trials, experience through occupational exposure, and in isolated tissue experiments in the laboratory. The importance of tolerance to the appropriate use of isosorbide dinitrate in the management of patients with angina pectoris has not been determined. However, one clinical trial using treadmill exercise tolerance (as an end point) found an 8-hour duration of action of oral isosorbide dinitrate following the first dose (after a 2-week placebo washout) and only a 2-hour duration of effect of the same dose after 1 week of repetitive dosing at conventional dosing intervals. On the other hand, several trials have been able to differentiate isosorbide dinitrate from placebo after 4 weeks of therapy and, in open trials, an effect seems detectable for as long as several months.

Tolerance clearly occurs in industrial workers continuously exposed to nitroglycerin. Moreover, physical dependence also occurs since chest pain, acute myocardial infarction, and even sudden death have occurred during temporary withdrawal of nitroglycerin from the workers. In clinical trials in angina patients, there are reports of anginal attacks being more easily provoked and of rebound in the hemodynamic effects soon after nitrate withdrawal. The relative importance of these observations to the routine, clinical use of isosorbide dinitrate is not known. However, it seems prudent to gradually withdraw patients from isosorbide dinitrate when the therapy is being terminated, rather than stopping the drug abruptly.

Information for Patients: Headache may occur during initial therapy with SORBITRATE. Headache is usually relieved by the use of standard headache remedies or by lowering the dose and tends to disappear after the first week or two of use.

Drug Interactions: Alcohol may enhance any marked sensitivity to the hypotensive effect of nitrates.

Isosorbide dinitrate acts directly on vascular smooth muscle, therefore, any other agent that depends on vascular smooth muscle as the final common path can be expected to have decreased or increased effect depending on the agent.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term studies in animals have been performed to evaluate the carcinogenic potential of this drug. A modified two-litter reproduction study in rats fed isosorbide dinitrate at 25 or 100 mg/kg/day did not reveal any effects on fertility or gestation or any remarkable gross pathology in any parent or offspring fed isosorbide dinitrate as compared with rats fed a basal-controlled diet.

Pregnancy Category C: Isosorbide dinitrate has been shown to cause a dose-related increase in embryotoxicity (increase in mummified pups) in rabbits at oral doses 35 and 150 times the maximum recommended human daily dose. There are no adequate and well-controlled studies in pregnant women. SORBITRATE should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when SORBITRATE is administered to a nursing woman.

Pediatric Use: The safety and effectiveness of SORBITRATE in children has not been established.

ADVERSE REACTIONS: Adverse reactions, particularly headache and hypotension, are dose related. In clinical trials at various doses, the following have been observed.

Headache is the most common (reported incidence varies widely, apparently being dose-related, with an average occurrence of about 25%) adverse reaction and may be severe and persistent. Cutaneous vasodilation with flushing may occur. Transient episodes of dizziness and weakness, as well as other signs of cerebral ischemia associated with postural hypotension, may occasionally develop (the incidence of reported symptomatic hypotension ranges from 2% to 36%). An occasional individual will exhibit marked sensitivity to the hypotensive effects of nitrates and severe responses (nausea, vomiting, weakness, restlessness, pallor, perspiration, and collapse) may occur even with the usual therapeutic dose. Drug rash and/or exfoliative dermatitis may occasionally occur. Nausea and vomiting appear to be uncommon. Case reports of clinically significant methemoglobinemia are rare at conventional doses of organic nitrates. The formation of methemoglobin is dose-related and, in the case of genetic abnormalities of hemoglobin that favor methemoglobin formation, even conventional doses of organic nitrate could produce harmful concentrations of methemoglobin.

DOSAGE AND ADMINISTRATION: For the treatment of angina pectoris, the usual starting dose for sublingual SORBITRATE is 2.5 to 5 mg, for chewable tablets, 5 mg, for oral (swallowed) tablets, 5 to 20 mg, and for controlled-release forms, 40 mg.

SORBITRATE should be titrated upward until angina is relieved or side effects limit the dose. In ambulatory patients, the magnitude of the incremental dose increase should be guided by measurements of standing blood pressure.

The initial dosage of sublingual or chewable SORBITRATE for prophylactic therapy in angina pectoris patients is generally 5 or 10 mg every 2 to 3 hours. Adequate controlled clinical studies demonstrating the effectiveness of chronic maintenance therapy with these dosage forms have not been reported.

SORBITRATE in oral doses of 10 to 40 mg given every 6 hours or in oral controlled-release doses of 40 to 80 mg given every 8 to 12 hours is generally recommended. The extent to which development of tolerance should modify the dosage program has not been defined. *The oral controlled-release forms of isosorbide dinitrate should not be chewed.*

DOSAGE FORMS AVAILABLE: Sublingual Tablets (2.5, 5, 10 mg). Chewable Tablets (5, 10 mg). Oral Tablets (5, 10, 20, 30, 40 mg); Sustained Action Tablets (40 mg).

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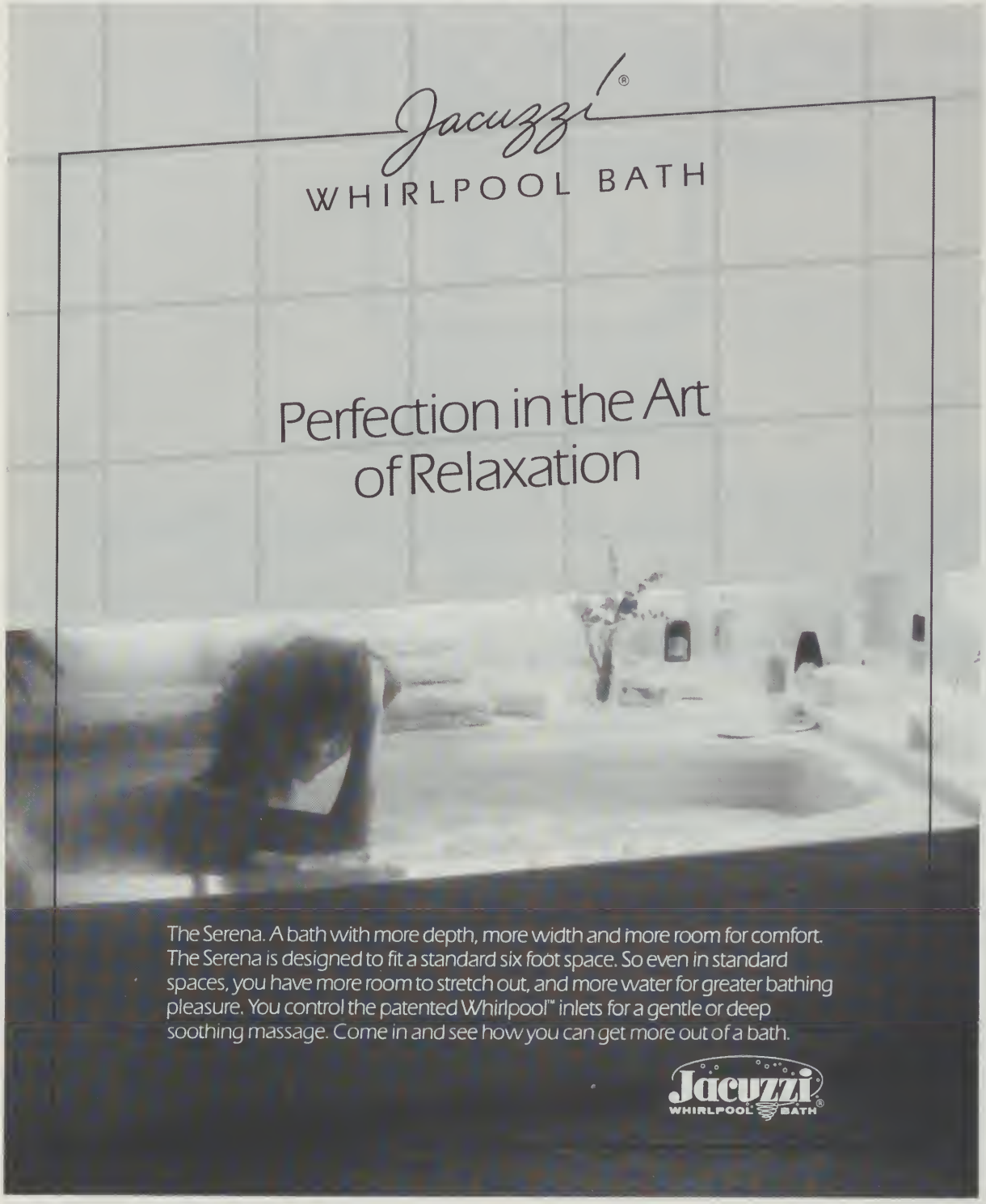
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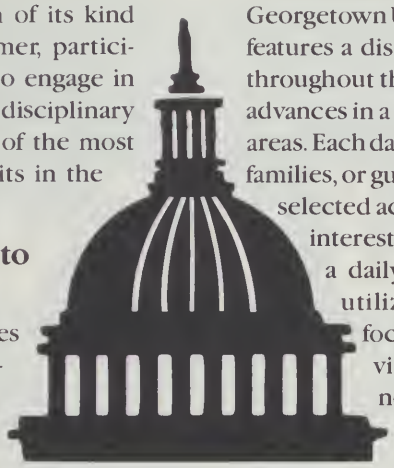
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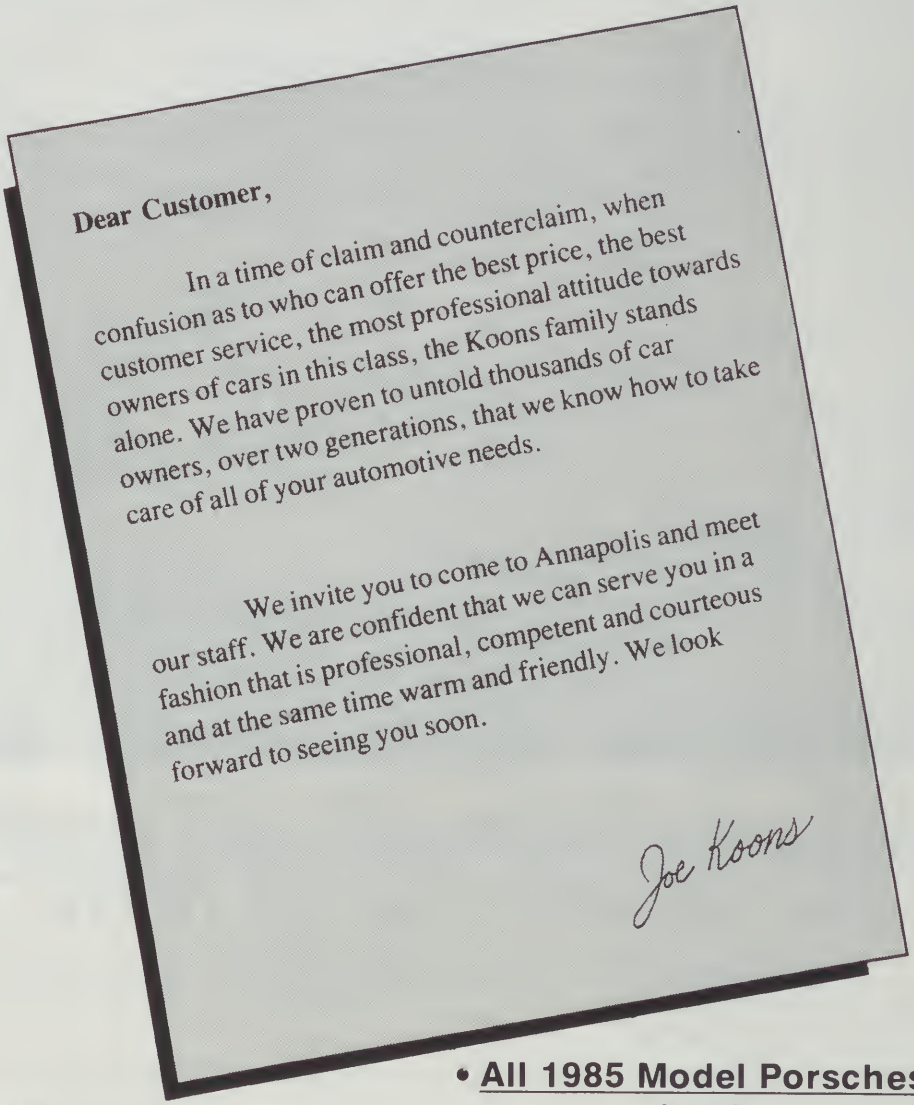
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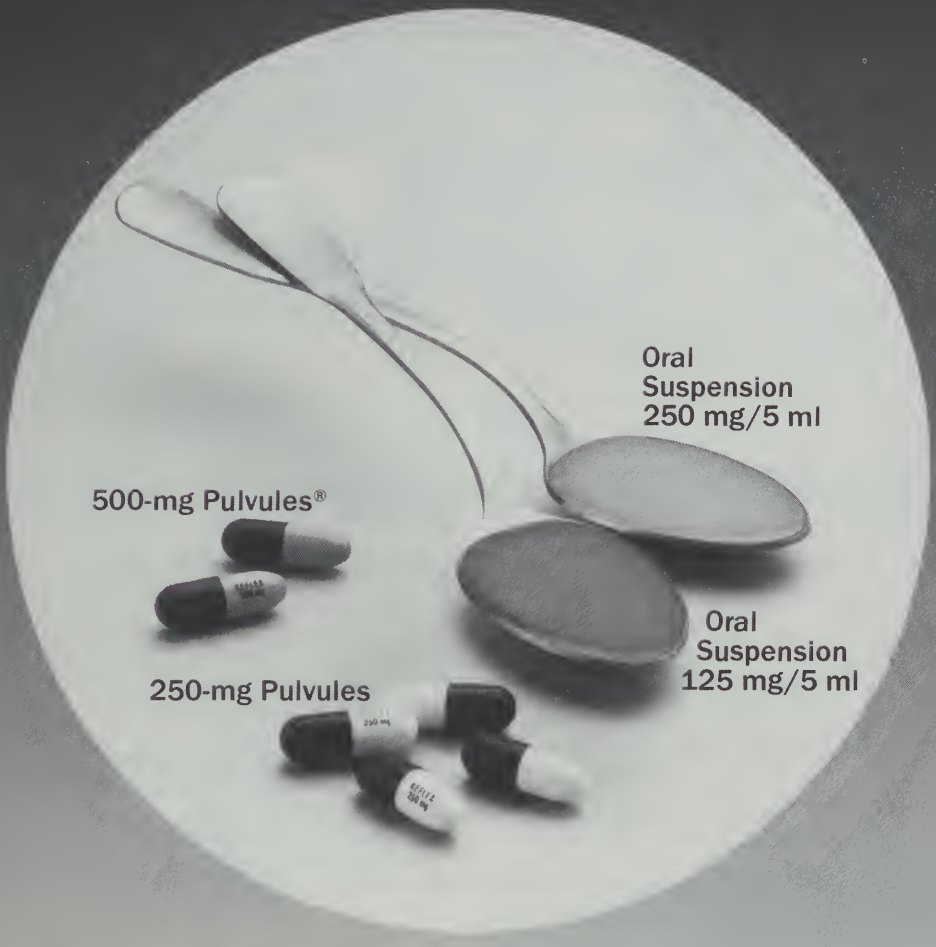
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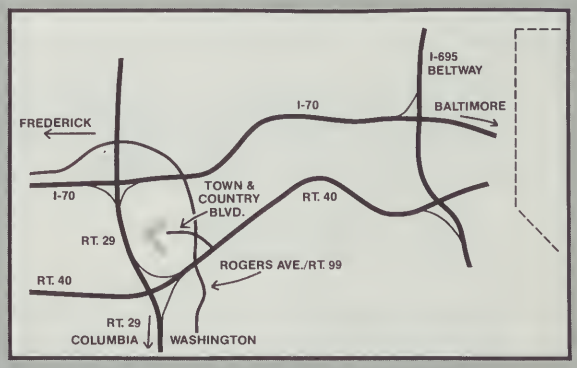


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Executive Director's Newsletter

May 1985

MEDICARE SUIT DISMISSED

Judge Sarah Evans Barker of the U.S. District Court for the Southern District of Indiana granted the government's Motion to Dismiss the AMA lawsuit challenging the constitutionality of the Medicare amendments in the 1984 Deficit Reduction Act.

The AMA plans to appeal this decision.

VERDICT IN ANTITRUST SUIT

The antitrust trial of John Ratino, M.D. in U.S. District Court for the District of Maryland against the Montgomery County Medical Society, DC Blue Shield, and individual physicians concluded in mid-April. The jury found in favor of the Defendants.

Dr. Ratino alleged that the Defendants were engaged in a conspiracy to fix fees by reviewing his fees and finding them to be above the usual-and-customary range.

LABORATORY PROFICIENCY TESTING

A review is under way to see if additional tests should be exempted from Health Department regulations requiring laboratory proficiency testing.

Physicians should let the Faculty office know of any exemptions they believe are appropriate.

FACULTY PARKING

To enable physicians to use the Faculty parking area while attending Faculty meetings or social events near Med-Chi, the Faculty has entered into a contract with Quille Parking. Physicians need only to identify themselves as members of the Faculty to the attendant on duty.

Previously, physicians often were prevented from using the parking area because spaces were occupied by others attending meetings and social events occurring in the neighborhood.

The Faculty is receiving a small income as well as better parking security from this arrangement.

PUBLIC RELATIONS PLAN

The Faculty's Council has approved the 1985-86 Public Relations Plan submitted by the Public Relations Committee. In addition to continuing projects established in 1984, the plan introduces a number of new objectives. Some of the new projects for the year will include implementing a media awards program, exploring the possibility of a health program on cable TV, and publishing a public relations newsletter in the Journal.

NEW SENATE AND HOUSE COMMITTEE

The State Senate and House of Delegates have established a Joint Committee on Health Care Cost Containment to review all regulations dealing with cost containment efforts enacted by the 1985 General Assembly session.

This group will be reviewing Utilization Review regulations, the Certificate of Need process, the Health Resources Planning Commission, the State Health Plan, specific studies, and any other issues relating to health care cost containment raised by various bills enacted by the General Assembly.

Members of this group include five Delegates and five Senators appointed by the House Speaker and Senate President. Staffing will be done by the Department of Legislative Reference and the Department of Fiscal Services.

1985 SEMIANNUAL MEETING

We have been able to negotiate an attractive week-long package to Bermuda and, therefore, have changed the dates of the 1985 Semiannual Meeting to Sunday, September 1 - Sunday, September 8. The price of $1,119 per person (double occupancy), plus $300 registration fee, includes round-trip airfare on nonstop charter flight from BWI Airport, 7 nights at the Southhampton Princess Hotel, breakfast and dinner each day, a 5-hour boat cruise with lunch, transfers between the airport and hotel in Bermuda, baggage handling, taxes, and gratuities. It does not include departure tax. The meeting dates include the Labor Day Holiday, which means only four regular working days' absence from your office. As always, we try to meet all requirements for tax deductibility for the Semiannual Meeting. Watch your mail for the announcement and registration forms.

PROFESSIONAL LIABILITY TELECONFERENCE

A national teleconference on Professional Liability will be held on Monday, June 3, at the Greater Baltimore Medical Center. The session will start at 1:00 p.m. and last two hours.

The growing number and severity of judgments against physicians, state level tort reform activities, patient safety, and risk management will be discussed. Panelists will answer call-in questions. For information on viewing in other areas, contact Elza Davis, 301-539-0872 or 800-492-1056.

John L. Sargeant
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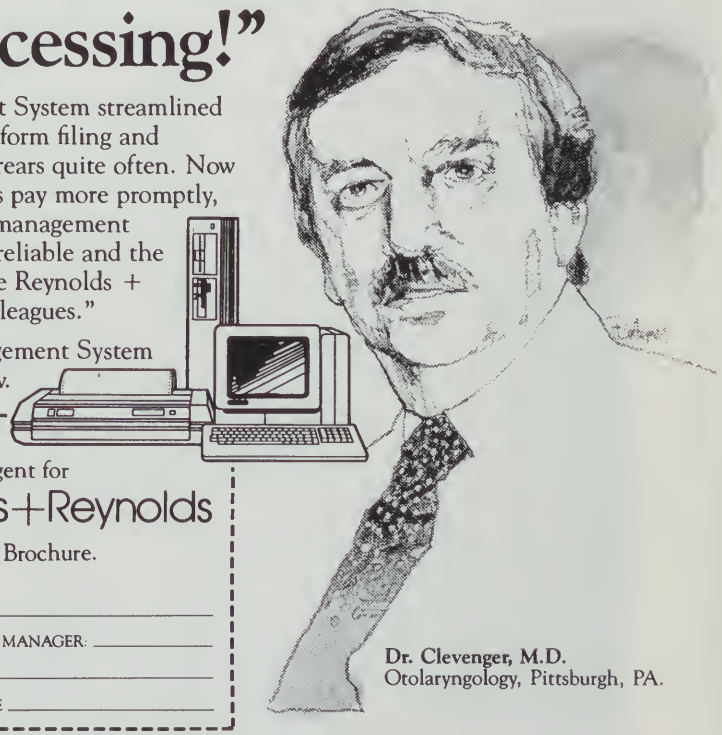
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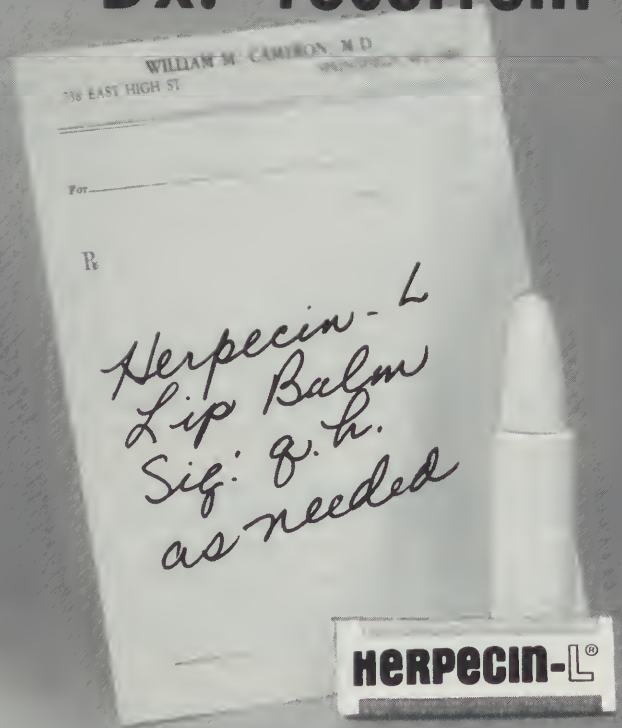
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Inside Med-Chi

The Workings of the Physician-Patient Relations Committee

Since the early days of medicine, physicians generally have enjoyed the trust and admiration of their patients. Today, however, the challenge of an increasingly skeptical public appears to require increased effort on the part of physicians to protect the quality of their patient relationships. The Faculty believes that the majority of physicians still maintain excellent relationships with their patients, but there is indeed a growing number of individuals who are less satisfied. More and more frequently the Faculty hears patient complaints such as "My doctor only spent 10 minutes with me, and it cost a fortune."

Negative sentiments regarding the physician-patient relationship are cited in the 1984 AMA Public Opinion Survey on health care issues as one of four major problem areas facing health care practitioners today. The survey indicates a slight but continuing decrease in the public's satisfaction with patient-physician interaction. The survey shows that in 1982, 54 percent of those polled believed doctors do not spend enough time with their patients, and 45 percent thought doctors do not explain things well enough. In 1983 these numbers increased respectively to 62 percent and 51 percent. In 1984 the number of people dissatisfied with their doctors' explanations increased even more to 56 percent.

With the growth of alternative medical delivery systems and the declining trend in the public's opinion of physicians, the quality of physician-patient interaction is crucial to maintaining a successful practice.

The Physician-Patient Relations Committee of the Medical and Chirurgical Faculty, organized in 1961, now spends most of its time addressing the public's dissatisfaction with the medical profession. The Committee reviews and investigates specific problems evolving from less-than-optimal physician-patient relationships. The number of cases received by the Faculty increases each year; a majority of complaints are referred for investigation by the Commission on Medical Discipline. The nature of these cases ranges from simple problems involving communication to serious questions about the quality of care. In some instances, complaints involving quality of care are found to be valid, and the physician in question is referred to the Faculty Peer Review Committee for extensive evaluation of his or her entire medical practice.

Of those cases referred by the Commission on Medical Discipline, a large number involve issues relating to professional fees. Because of antitrust implications, the Faculty will investigate only fee-related complaints referred to the Faculty by the Commission. On investigation the majority of fee-related complaints are determined to be unfounded. This emphasizes the importance of proper communication and discussion of fees in advance.

Other frequent complaints involve quality-of-care issues, second opinions, and access to medical records. The Committee investigates 200 such non-fee-oriented complaints a year.

Although most cases involve problems between physicians and patients, the committee also investigates grievances between physicians. These disputes frequently involve the referral of patients and the distribution of medical records when a practice separates. When problems evolve from a physician leaving an established practice, the committee generally rules that the records of those patients primarily treated by the departing physician should be made available to that physician within a reasonable time. It is also noted that Maryland law requires that medical records must be provided to succeeding physicians with proper authorization of the patient.

In cases of patient complaints or grievances, the committee notifies the physician in question of the complaint. The physician is required to respond in writing and to forward copies of the medical record. The statutes allow that such information may be forwarded to a medical review committee without patient's authorization. Of the cases received, 70 percent are resolved at the committee level on the basis of documentation. However, in some cases, the committee will interview the physician and/or the complainant in order to arrive at a better conclusion.

On completion of the investigation, the committee submits a report to the Commission on Medical Discipline recommending specific action. These recommendations range from closing the case without action to formal action against the physician's license. The Commission, by law, has the final word on what disciplinary action is exercised. By statute all investigatory activity by a medical review committee (including records, reports, and so on) is confidential and may not be admitted as evidence in a civil action. Formal actions of the Commission, when completed, are public record and are published in the *Maryland Medical Journal.*

Today, the medical profession is challenged by the need for effective interaction and communication between the physician and patient. The communication that takes place in the doctor's office can establish a patient's long-term satisfaction and confidence in his or her doctor and can lessen the chance for misunderstandings that lead to complaints.

Some steps can be taken to insure good physician-patient relationships:

- Clearly explain all fees in advance.

Public Relations Committee
James E. Bell MD, Chairman

- Thoroughly explain all surgical procedures in advance.
- Adequately train staff to address discrepancies between professional fees and third-party reimbursement.
- Offer a mechanism to deal with patient complaints within the office.
- Monitor your office staff to make sure they are polite and sensitive.
- Remain accessible to your patients. Consider whether your staff is being overly protective of your time by preventing patient access to you.
- In the hospital setting, maintain as much personal contact with the patient as is reasonably possible.

The development of interpersonal communication and interaction between the doctor and patient is essential in revitalizing the physician-patient relationship.

NINA C. CASEY
Public Relations/Membership Coordinator

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Your Medical Faculty at Work

The Council in a relatively brief session on Thursday, March 28, 1985, adopted a Public Relations Plan for 1985/86, at the suggestion of the Public Relations Committee and on recommendation of the Executive Committee. The Plan provides for increased emphasis on public relations activity as a first step toward a greatly expanded public relations program. Copies of this proposal for 1985/86 can be obtained by contacting Nina Casey at the Faculty Office.

Council also directed the Bylaws Committee to prepare an appropriate amendment to establish a Standing Committee on Computers in Medicine. Pending legal clearance, the Council delayed formal endorsement of the Maryland MEDSIG program.

It also received various information items; approved support of the Maryland Health Convocation in the amount of $2,000; and heard updates on various legal matters pending in the courts.

JOHN SARGEANT CAE
Executive Director

. . . in the June issue of MMJ . . .

Miasmatic and Microscopic Explanation of Disease

Quantitative Assessment of Burn Wound Progress

The Library Page

Your Faculty Library's Place in the Expanding Faculty Facilities

Last month an article in the *Maryland Medical Journal* announced the beginning of construction for Med-Chi's expanded facilities on Cathedral Street. The former School #49, next to the Faculty building, is to be restored and remodeled into modern offices. When most of the Faculty's business operations are moved into the new building, and the financial and computer operations are moved to the first floor of the present building, the library will expand upward to the present third and fourth floors. The plans also call for remodeling the library's basement stack area to include space-saving, compacted shelving. The net effect of these changes will be to reduce the now overcrowded and congested library work areas and to increase the library's total stack capacity by about 30 per cent.

The new library will have a very different appearance. Most of the shelving in the present reading room will be removed, and the room will be restored to its previous grandeur. The staff desks, typewriters, computers, printers, and telephones will be moved to offices so the room will again be a quiet place to study or to relax before and between meetings. Current journal issues will continue to be displayed there. The reading room also will be available as a meeting room for more formal Faculty functions. The room will be furnished with several fine antiques left to the Faculty many years ago in the estate of John Ruhrah MD. In addition, several very fine pieces of furniture have been promised to the library by Louise Krause, sister of the late Louis A.M. Krause MD. The reading room is named for Dr. Krause, a devoted supporter of the library who chaired the Faculty's Library Committee for many years. The two beautiful oriental rugs will remain: one came from the estate of Dr. Ruhrah; the other was a gift to the library by a current member of the Library Committee, Marco Clayton MD, in memory of his parents, Dr. and Mrs. Samuel Clayton.

The MEDLINE operation, reference collection, and reference desk will be moved to offices adjoining the reading room. Library staff will be available to assist visitors, but without the constant noise of telephones and office equipment that makes it difficult for anyone to concentrate in the reading room.

Housed on the first two floors of the stacks will be the library's main collection of textbooks and monographs. The entire collection is to be recatalogued, making it easier for library users to browse. A circulation desk will be located at the entrance to the stacks.

Photocopy and interlibrary loan operations will be moved to a basement office. The entire bound journal collection will be housed in the basement stack area. The new journal stacks will be on wheels so all the shelves can be pushed together, allowing almost twice as much space for journals. Shelves can be opened and closed at any point to gain access to the journals.

Offices and a work room on the third floor will house the library's technical services department, including all the library services currently sold to hospital libraries, that is, book and journal acquisitions and cataloging. The library's computer also will be on the third floor.

The Faculty's rare book collection will occupy the top two floors of the current stack area. This area will be kept locked. An office for the History of Medicine and Archives Librarian will be on the third floor, as well as a supervised room where scholars and researchers can use materials from the Faculty's collection. The fourth floor of the Faculty building will serve as a library work area and will include a book processing area, a bindery, and a book and paper preservation laboratory.

In addition to the improved reading room described above, these changes will also mean neater, cleaner, and less cluttered work areas for the library staff. The library materials will be less scattered and easier to find. The Faculty's rare books and archives will be more appropriately housed and protected and more available for researchers and scholars.

In helping plan for the new Faculty offices and the changes in the present building, I had opportunity to review all blue prints and plans drawn up for expanded Faculty facilities. When the present building was completed in 1909, the Faculty staff was two full-time and three part-time employees. Now, 75 years later, at least 35 full-time and 4 part-time employees work in this same building. As early as the 1920s it was said the present building was not large enough. Since then there have been at least four proposed expansions and for each, drawings and blueprints were prepared. There was a major renovation in the early 1960s, but no expansion.

In my association with the Faculty, working with its records and history, the Faculty's past, present, and future have taken on a somewhat personal character. I have frequently written and talked about the Faculty's current activities and how these are related to what it did in the past and to the charges given the Faculty in its charter of 1798. Working with the architect in planning this expansion has reinforced these thoughts. In about 18 months ceremonies to dedicate the new addition to the Faculty headquarters and rededicate the present building will be more than just the completion of a dream that began 65 years ago. It will be another

Medical and Chirurgical Faculty of the State of Maryland Library, 1211 Cathedral Street, Baltimore, MD 21201. Joseph E. Jensen, Librarian.

milestone in the nearly 200 year old heritage of Med-Chi.

JOSEPH E. JENSEN
Librarian

Selected Medical Literature Searches

The following are among the computerized medical literature searches provided to Med-Chi members during February 1985.

	Number of Citations
1. Adie's syndrome	20
2. Attention deficit disorder	43
3. Chemotherapy for Karposi's sarcoma	18
4. Closing the hospital medical staff	13
5. Contrast media hypersensitivity	22
6. Drug interactions with food	31
7. Genital warts and cervical neoplasms	27
8. Humanism and medicine	14
9. Occurrence, treatment, and mortality in Reye's syndrome	28
10. Skin grafts and burns	29

If you would like a copy of one of these searches or a search run on any biomedical topic, call or write the library.

SUSAN E. HARMAN
Reference and Circulation Librarian

Hotline Numbers for Impaired Professionals

Physicians—727-0120
Dentists—859-0667
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Pharmacists—727-0746 or 528-7513

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For latest information on Med-Chi Annual and Semiannual Meetings, read the **Journal** every month.

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Baltimore County Medical Association

The Orientation Meeting for New Members of the Association was held on February 12, 1985. The Chairman of the Orientation Committee, Vernon M. Smith MD, was also the Moderator for the dinner meeting. Other participants were Louis C. Breschi MD, Medical Ethics; Charles F. Hoesch MD, Peer Review and Drug Control Considerations; John A. Engers, Jr. MD, Professional Review Organization; John M. Krager MD, Health Department Services; Sal Fascina MD, JD, Malpractice & Professional Liability, and Seymour Weiner MD, Consultations; and John W. Buckley MD, Physician and Third Party Payors.

The regular monthly meeting of the Association held on February 20 was called to order by the President, Dr. J. David Nagel. Under the Board of Governors report, Thomas Allen MD was elected to serve in the House of Delegates. The Association now has 19 delegates. The Public Relations Committee reported it will continue its programs stressing that "Your Doctor Cares." On proper motion, the report of the Board of Governors was accepted.

Dr. Nagel and Dr. Thomas Allen recently attended the National Leadership Conference sponsored by the AMA. Dr. Nagel reported there was not the "gloom and doom" felt this year as there was at the previous conference. Senator Durenberger, author of the Medicare Bill, reflected the concerns of the federal government regarding escalating health care costs and appeared to be sympathetic to the problems facing the medical profession. Dr. Nagel anticipates the government working with the medical profession in attempts to reach a solution. Following the adjournment of the business meeting, Dr. Ibrahim Razzak introduced Dr. Jeremy Altman who gave an excellent presentation on "Interventional Radiology." A tour of the new Oncology Unit at GBMC followed the meeting.

The Legislative dinner of the BCMA was held in Annapolis February 25. John Sargeant and Elza Davis joined with members of the Board of Governors and the Legislative Committee in entertaining members of the Legislature.

ALFONSO JANOSKI MD
Editor

One Minute with Diabetes

Doctor, my 20-year-old son has had brittle diabetes for ten years. He recognized hypoglycemic reactions easily and treated them with fruit juice or glucose tablets without any problem. In the past week he has had three episodes of hypoglycemic coma that came on without his recognizing any symptoms of hypoglycemia.

After further inquiry, it was learned that his headache doctor started propranolol 20 mg. q.i.d. Betaadrenergic agents can block the epinephrinelike symptoms of hypoglycemia (nervousness, tachycardia, sweating) causing insulin-dependent diabetics to have severe hypoglycemic reactions without warning.

This patient might be tried on a slow channel blocker or another drug (other than a beta blocker) recommended for headache prevention.

DeWITT E. DeLAWTER MD

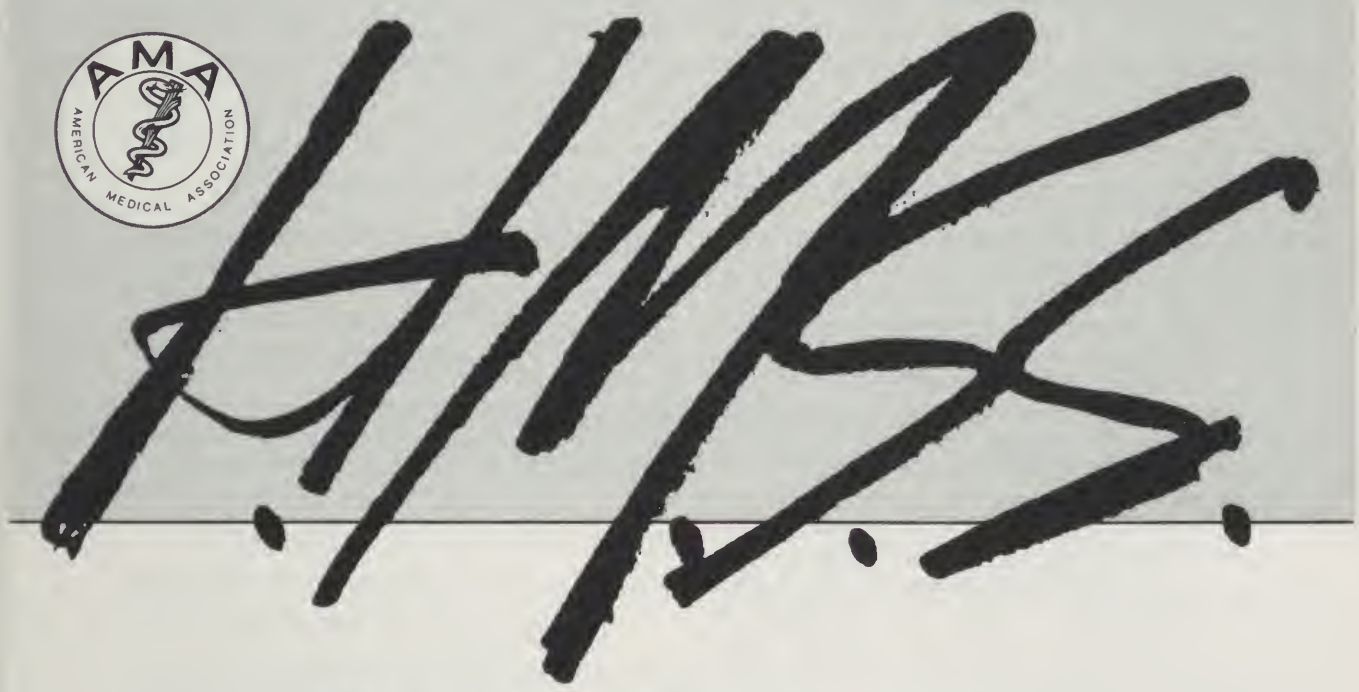
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Maryland Oncology Newsletter

Screening and Early Detection of Cutaneous Melanoma

JOSEPH W. BURNETT MD and E. GEORGE ELIAS MD

It is estimated that over 17,000 new cases of skin melanoma will be diagnosed this year, and over 7,000 patients will die of this disease in the U.S. This indicates that over one third of the patients will succumb to the disease each year. Worldwide, the incidence and mortality rates of melanoma are increasing rapidly. Early detection followed by surgical management can yield over 80 percent cure rates.

Although cutaneous melanoma occurs primarily in light-skinned individuals with freckles, blue eyes, and red hair (1:100), it is frequently diagnosed in all whites and to much less extent in blacks (20:1). In blacks, it usually appears in the light-skin areas but is found on the plantar surface of feet and, less frequently, on the palms. Less than 10 percent of the patients with melanoma may present with vitiligo, that is, large blanched areas of the skin of the body.

The relationship between sun exposure and development of skin melanoma was suggested by Queensland Melanoma Task Force in Australia, where a higher incidence of melanoma was noted in the white population living near the tropical zone. In addition, some familial tendency has been noted as 10 percent of the melanoma patients have other family members afflicted by the disease. Other predisposing skin lesions are hairy nevi, which have a 30 percent chance of developing melanoma. Junctional nevi on palms, soles, and genitalia also should be removed as these may predispose to the development of melanoma. Halo nevi are believed to be benign nevi being spontaneously rejected.

The diagnosis of cutaneous melanoma is suspected from certain clinical criteria. A pigmented skin lesion with convoluted border, irregular or elevated surface, or different colors (that is, a combination of red, blue, white, brown, or black) is suspicious. It may develop *de novo* or in a pre-existing mole that becomes larger, changes in color, borders, or surface.

A benign mole usually has a regular margin, smooth surface, and a single color. However, some benign skin lesions (such as keratotic lesions) may deviate from these three benign characteristics. Other types of melanoma may present as subungual melanoma, that is, under the nail bed (in blacks and whites) or mucosal melanoma in the mucosa of ectodermal origin such as anal canal, vagina, vulva, nasal cavity, nasopharynx, oral cavity, and larynx. Melanoma also may originate in the eyes from the iris, choroid plexus, or eye appendages, such as eyelid. Meningeal melanomas also have been reported.

Amelanotic melanoma is a nonpigmented skin lesion; it may have a poor prognosis if undiagnosed. Diagnosis is confirmed by biopsy of any of the suspicious lesions. It is highly recommended not to excise the dome of the lesion (shave-type biopsy) but to do incisional biopsy including all layers of skin, such as by Martin punch biopsy instrument, or better excisional biopsy that includes 1 mm around the lesion and the whole skin thickness. This is of utmost importance as the level of invasion reflects on the prognosis and may determine the extent of the definitive surgical excision later.

A Pigmented Lesion Clinic has been opened at the University of Maryland Medical System to diagnose and treat patients with malignant melanoma of the skin and to identify and follow those patients at high risk of developing the disease. This newly opened clinic is the only one in Maryland and one of the few in the country. Directed by Joseph W. Burnett MD, head of the Division of Dermatology, the clinic will use a team approach including services of Dermatologists, Surgical and Medical Oncologists, Pathologists, and Psychiatrists. During the initial visit to the clinic, a high-risk patient is examined and evaluated by a physician and polaroid photographs of all moles are taken. These photographs are kept in the patient's chart and are used as a comparison for succeeding annual photographs. If during the initial visit a lesion is suspected, the patient is seen by a surgeon and pathologist, and a biopsy is taken. Such multidisciplined approach will assure optimal results. The clinic is located at the University of Maryland Hospital. For information call 301-528-5768.

If you have any questions, please write or call the Surgical Oncology Program at the University of Maryland Medical System, Room N13E02, Baltimore, MD 21201 (301-528-5224).

PHYSICIAN PLACEMENT SERVICE

The Medical and Chirurgical Faculty of the State of Maryland maintains a Placement Service for the convenience of Maryland physicians, hospitals and communities in search of candidates for positions available in our state. A detailed description of such opportunities should be forwarded to the Physician Placement Service, 1211 Cathedral St., Baltimore, MD 21201; telephone 1-301-539-0872.

Physicians wishing to locate in Maryland are invited to submit a resume to be kept on file with the Physician Placement Service. Candidates are requested to inform the Faculty when they are no longer available for consideration for opportunities which might be available in Maryland.

Journal announcements on the Classified Advertising page for Physician Placement Service are charged at the regular Classified Advertising rate.

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MAY 1985

CHANGE IN DTP VACCINE RECOMMENDATIONS

Connaught Laboratories announced April 25th they have resumed full scale distribution of DTP vaccine and have 2.2 million doses for immediate shipment. In view of this, the CDC, ACIP and AAP now recommend the 4th and 5th doses of DTP be resumed and children whose doses were deferred be recalled and brought up to date, particularly children scheduled to enter kindergarten in the fall.

LYME DISEASE
(LYME ARTHRITIS, ERYTHEMA CHRONICUM MIGRANS WITH POLYARTHRITIS, TICK-BORNE MENINGOPOLYNEURITIS)

A geographic clustering of arthritis cases in several rural communities in southeastern Connecticut in 1975 led to the recognition of Lyme disease. Endemic foci now include wooded locations along the coast from Massachusetts to Virginia and in certain other non-contiguous states.

This tick-borne spirochetal zoonotic disease is characterized by distinctive erythema chronicum migrans (ECM), systemic symptoms, polyarthritis, and neurological and cardiac involvement occurring in varying combinations. A spirochete isolated from the tick Ixodes dammini was confirmed as the agent of Lyme disease in 1983.

Lyme disease typically occurs in the summer and early fall. Three to 32 days following a tick bite, a red macule or papule appears at the bite site which expands into a large annular (6-16 cm) erythematous non-pruritic lesion. The mucous membranes are not involved. The lesions are usually accompanied by malaise, fatigue, chills, fever ($38^{\circ}C$ to $39.5^{\circ}C$), headache, stiff neck or backache and less often diffuse myalgia, nausea, vomiting and sore throat. Lymphadenopathy and splenomegaly are occasionally present.

Usually the skin lesion fades in 3 to 4 weeks and recovery is complete. In some patients, further immune complex-mediated inflammatory responses develop. Within weeks to months following onset of ECM, neurological abnormalities can occur (e.g., aseptic meningitis, encephalitis, chorea, cerebellar ataxia, cranial neuritis including facial palsy, motor or sensory radiculoneuritis). Cardiac conduction abnormalities may occur within a few weeks after the onset of ECM. Weeks or years (usually 4 weeks) after onset, swelling and pain in large joints, especially the knees, may develop and recur for several years. Lyme arthritis is seen in one-half of the patients. Chronic arthritis may occur in 10%.

The diagnosis is suggested by the presence of the distinctive skin lesions and the subsequent development of neurologic, cardiac and arthritic manifestations. In the absence of the skin lesions, a geographic clustering of arthritis cases in summer and early fall is suggestive. All persons are probably susceptible. The age range of cases is 2 to 88 years. Reinfections have occurred. There is no evidence of person-to-person transmission.

Specific IgM antibody titers usually reach a peak between the third and sixth week after the onset of disease. Specific IgG antibody titers rise slowly and are usually at their highest months later when arthritis is present. Indirect fluorescent antibody titers $\geq$1:256 on a single serum or fourfold rise between acute and convalescent titers confirm the diagnosis.

For diagnostic services, one Vacutainer tube of 5-7 ml clotted blood for serological testing and one of citrated blood for culture is required. CSF and skin biopsy specimens can also be submitted in a sterile container. A 3 mm punch biopsy of the skin can be taken at either the center or leading edge of ECM lesion, placed in a sterile container without preservative and sent promptly to the Laboratories Administration. Isolation techniques require at least two weeks for results. Serology will be performed within 48 hours after receiving the specimen in the laboratory. (For further information, please call: 383-3361.)

The ECM responds to penicillin 250,000 units or 250 mg tetracycline (or erythromycin) four times a day for 7 to 10 days. Patients treated with pencillin or tetracycline have a shorter duration of ECM than untreated patients. Antibiotic treatment may prevent or lessen the severity of the cardiac, neurologic or arthritic sequelae. If these occur, management is empiric.

Reporting of Lyme disease is encouraged.

References are available upon request.

Rocky Mountain Spotted Fever
(New World Spotted Fever, Tick-Borne Typhus Fever)

Maryland accounted for 26 cases (0.61/100,000) of the 847 cases (0.36/100,000) of Rocky Mountain spotted fever reported nationally in 1984. Eleven jurisdictions of Central (Cecil to Frederick counties) and Southern Maryland reported 10 cases in May, 6-June, 6-July, 2-August and 1 in September.

This prototype spotted fever disease caused by *Rickettsia rickettsii* is usually transmitted by the bite of an infected tick. A tick attachment of 4 to 6 hours is necessary for the rickettsiae to become reactivated and capable of infecting man. Contaminating the skin by crushing the tissue or feces of the tick may also result in infection. The dog tick *Dermacentor variabilis* is the common Maryland vector and the Lone Star tick *Amblyomma americanum* is a possible but rare vector. There is no person-to-person transmission.

Transmission parallels the tick season and the incubation period is from 3 to 14 days. A sudden onset of moderate to high persistent fever, malaise, deep myalgia, severe headache, chills and conjunctivitis is characteristic. A typical unraised rash appears first on the extremities on the third day (1-7 febrile day) and soon includes the palms, soles and most of the body. Petechia and hemorrhages are common. Absent, undetected or delayed appearance of the rash contributes to a delay in diagnosis and treatment. Atypical measles, meningococcemia and enteroviral infections should be considered in the differential diagnosis.

With prompt recognition and early treatment death is uncommon but reaches 15% - 20% with nonspecific therapy. Daily oral tetracycline or chloramphenicol (for children under 8 years and pregnant women) is indicated until the patient is afebrile for at least 2 days (for a total of usually 4-5 days). Reinfection or recrudescense are not known to occur.

The probability of developing Rocky Mountain spotted fever by a person from whom an attached tick was removed is low and on such occasions chemoprophylaxis is not indicated.

Laboratory confirmation must not delay therapy. Serological tests confirming the diagnosis are the following: single complement fixation (CF) titer of 1:16 or higher or fourfold rise in the CF, IFA, microagglutination (MA), latex agglutination (LA), or indirect hemagglutination (IHA) assays. Submitted prepared frozen tissue sections which are mounted and fixed will be examined by direct FA procedures for the agent.

Persons with high risk activities in endemic areas should avoid tick bites and remove ticks before reactivation of the rickettsiae occurs. They should be instructed to: 1) avoid brushy and tall grass areas; 2) remove ticks (with tweezers when possible) and wash hands; 3) dress with long pants and sleeves, buttoned-up and tucked-in (including pants into socks) and wide brimmed hat; 4) use tick repellents; and 5) record the date of each tick attachment.

Rocky Mountain spotted fever is a reportable disease.

References available upon request.

Multicenter Pertussis Surveillance

After a few months of quiescence, pertussis activities have started again. January and February marked the highest number of reports as well as laboratory confirmed cases. Several interesting findings have been observed during the past 9 months of active surveillance in Baltimore City and Baltimore County. Following are the summaries of the preliminary results:

1. A total of 206 cases of clinically suspected or diagnosed pertussis were reported from July 1984 to March 1985 from the study area. Household investigations were completed in 124 (60%) of the

cases (Table 1). Eighty-two (82) households were not investigated due to various reasons, such as parent's refusal, physician's change of diagnosis, inability to reach the family, etc. (Table 2). A total of 32 (4.7%) laboratory confirmed cases were identified among the 683 persons cultured.

2. The 32 laboratory confirmed cases were identified from 21 households, 12 from reported (index) cases and 20 from household investigations.

3. In these 21 households with laboratory confirmed case(s), four had cases confirmed both in the reported (index) case and household contact, 8 in reported cases only and 9 in household contacts only.

4. Twenty-four persons were confirmed as having *B. pertussis*, seven *B. parapertussis*, and one individual as having both *B. pertussis* and *B. parapertussis*.

5. The eight individuals with *Bordetella parapertussis* isolated were from six households. Among these six households, three showed clusters of *B. parapertussis* and *B. pertussis* in the same household either in different household members and/or in the same individual.

Table 1. Reported Cases and Household Investigations by Month, July 1984 - March 1985

Year/Month	Reported #Cases	Household Investigation Cases	#Contacts	Lab. Confirmation # Persons
1984				
July	19	15	67	6
August	35	21	58	5
September	19	8	22	0
October	13	7	14	0
November	14	10	28	0
December	15	8	23	0
1985				
January	16	7	17	4
February	40	25	84	11
March	35	23	87	6
TOTAL	206	124	377	32

Table 2. Reasons for No Household Investigation

Physicians' change of diagnosis	15
Parents' refusal	34
Unable to reach the family	19
Out of study area	13
Other	1
TOTAL	82

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J-4044 January 1984

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Please see brief summary of prescribing information on the next page for further details.

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BRIEF SUMMARY *(FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE CIRCULAR.)*

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DESCRIPTION. Inderal LA is formulated to provide a sustained release of propranolol hydrochloride. Inderal LA is available as 80 mg, 120 mg, and 160 mg capsules.

CLINICAL PHARMACOLOGY. INDERAL is a nonselective beta-adrenergic receptor blocking agent possessing no other autonomic nervous system activity. It specifically competes with beta-adrenergic receptor stimulating agents for available receptor sites. When access to beta-receptor sites is blocked by INDERAL, the chronotropic, inotropic, and vasodilator responses to beta-adrenergic stimulation are decreased proportionately.

INDERAL LA Capsules (80, 120, and 160 mg) release propranolol HCl at a controlled and predictable rate. Peak blood levels following dosing with INDERAL LA occur at about 6 hours and the apparent plasma half-life is about 10 hours. When measured at steady state over a 24-hour period the areas under the propranolol plasma concentration-time curve (AUCs) for the capsules are approximately 60% to 65% of the AUCs for a comparable divided daily dose of INDERAL tablets. The lower AUCs for the capsules are due to greater hepatic metabolism of propranolol, resulting from the slower rate of absorption of propranolol. Over a twenty-four (24) hour period, blood levels are fairly constant for about twelve (12) hours then decline exponentially.

INDERAL LA should not be considered a simple mg for mg substitute for conventional propranolol and the blood levels achieved do not match (are lower than) those of two to four times daily dosing with the same dose. When changing to INDERAL LA from conventional propranolol, a possible need for retitration upwards should be considered especially to maintain effectiveness at the end of the dosing interval. In most clinical settings, however, such as hypertension or angina where there is little correlation between plasma levels and clinical effect, INDERAL LA has been therapeutically equivalent to the same mg dose of conventional INDERAL as assessed by 24-hour effects on blood pressure and on 24-hour exercise responses of heart rate, systolic pressure and rate pressure product. INDERAL LA can provide effective beta blockade for a 24-hour period.

The mechanism of the antihypertensive effect of INDERAL has not been established. Among the factors that may be involved in contributing to the antihypertensive action are (1) decreased cardiac output, (2) inhibition of renin release by the kidneys, and (3) diminution of tonic sympathetic nerve outflow from vasomotor centers in the brain. Although total peripheral resistance may increase initially, it readjusts to or below the pretreatment level with chronic use. Effects on plasma volume appear to be minor and somewhat variable. INDERAL has been shown to cause a small increase in serum potassium concentration when used in the treatment of hypertensive patients.

In angina pectoris, propranolol generally reduces the oxygen requirement of the heart at any given level of effort by blocking the catecholamine-induced increases in the heart rate, systolic blood pressure, and the velocity and extent of myocardial contraction. Propranolol may increase oxygen requirements by increasing left ventricular fiber length, end diastolic pressure and systolic ejection period. The net physiologic effect of beta-adrenergic blockade is usually advantageous and is manifested during exercise by delayed onset of pain and increased work capacity.

In dosages greater than required for beta blockade, INDERAL also exerts a quinidine-like or anesthetic-like membrane action which affects the cardiac action potential. The significance of the membrane action in the treatment of arrhythmias is uncertain.

The mechanism of the antimigraine effect of propranolol has not been established. Beta-adrenergic receptors have been demonstrated in the pial vessels of the brain.

Beta receptor blockade can be useful in conditions in which, because of pathologic or functional changes, sympathetic activity is detrimental to the patient. But there are also situations in which sympathetic stimulation is vital. For example, in patients with severely damaged hearts, adequate ventricular function is maintained by virtue of sympathetic drive which should be preserved. In the presence of AV block, greater than first degree, beta blockade may prevent the necessary facilitating effect of sympathetic activity on conduction. Beta blockade results in bronchial constriction by interfering with adrenergic bronchodilator activity which should be preserved in patients subject to bronchospasm.

Propranolol is not significantly dialyzable.

INDICATIONS AND USAGE. Hypertension: INDERAL LA is indicated in the management of hypertension; it may be used alone or used in combination with other antihypertensive agents, particularly a thiazide diuretic. INDERAL LA is not indicated in the management of hypertensive emergencies.

Angina Pectoris Due to Coronary Atherosclerosis: INDERAL LA is indicated for the long-term management of patients with angina pectoris.

Migraine: INDERAL LA is indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established and propranolol is not indicated for such use.

Hypertrophic Subaortic Stenosis: INDERAL LA is useful in the management of hypertrophic subaortic stenosis, especially for treatment of exertional or other stress-induced angina, palpitations, and syncope. INDERAL LA also improves exercise performance. The effectiveness of propranolol hydrochloride in this disease appears to be due to a reduction of the elevated outflow pressure gradient which is exacerbated by beta-receptor stimulation. Clinical improvement may be temporary.

CONTRAINDICATIONS. INDERAL is contraindicated in 1) cardiogenic shock; 2) sinus bradycardia and greater than first degree block; 3) bronchial asthma; 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with INDERAL.

WARNINGS. CARDIAC FAILURE: Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or INDERAL should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of INDERAL therapy. Therefore, when discontinuance of INDERAL is planned the dosage should be gradually reduced over at least a few weeks, and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If INDERAL therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute INDERAL therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema)— PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. INDERAL should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY: The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

INDERAL (propranolol HCl), like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, e g dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOGLYCEMIA: Beta-adrenergic blockade may prevent the appearance of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more difficult to adjust the dosage of insulin.

THYROTOXICOSIS: Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol does not distort thyroid function tests.

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS. *General:* Propranolol should be used with caution in patients with impaired hepatic or renal function. INDERAL (propranolol HCl) is not indicated for the treatment of hypertensive emergencies.

Beta adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should be told that INDERAL may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

Clinical Laboratory Tests: Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS. Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if INDERAL is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

Pregnancy: Pregnancy Category C. INDERAL has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose.

There are no adequate and well-controlled studies in pregnant women. INDERAL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: INDERAL is excreted in human milk. Caution should be exercised when INDERAL is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS. Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: bradycardia; congestive heart failure; intensification of AV block; hypotension; paresthesia of hands; thrombocytopenic purpura; arterial insufficiency, usually of the Raynaud type.

Central Nervous System: lightheadedness; mental depression manifested by insomnia, lassitude, weakness, fatigue; reversible mental depression progressing to catatonia; visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Gastrointestinal: nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory: bronchospasm.

Hematologic: agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-Immune: In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: alopecia, LE-like reactions, psoriasiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

DOSAGE AND ADMINISTRATION. INDERAL LA provides propranolol hydrochloride in a sustained-release capsule for administration once daily. If patients are switched from INDERAL tablets to INDERAL LA capsules, care should be taken to assure that the desired therapeutic effect is maintained. INDERAL LA should not be considered a simple mg for mg substitute for INDERAL. INDERAL LA has different kinetics and produces lower blood levels. Retitration may be necessary especially to maintain effectiveness at the end of the 24-hour dosing interval.

HYPERTENSION—*Dosage must be individualized.* The usual initial dosage is 80 mg INDERAL LA once daily, whether used alone or added to a diuretic. The dosage may be increased to 120 mg once daily or higher until adequate blood pressure control is achieved. The usual maintenance dosage is 120 to 160 mg once daily. In some instances a dosage of 640 mg may be required. The time needed for full hypertensive response to a given dosage is variable and may range from a few days to several weeks.

ANGINA PECTORIS—*Dosage must be individualized.* Starting with 80 mg INDERAL LA once daily, dosage should be gradually increased at three to seven day intervals until optimum response is obtained. Although individual patients may respond at any dosage level, the average optimum dosage appears to be 160 mg once daily. In angina pectoris, the value and safety of dosage exceeding 320 mg per day have not been established.

If treatment is to be discontinued, reduce dosage gradually over a period of a few weeks (see WARNINGS).

MIGRAINE—*Dosage must be individualized.* The initial oral dose is 80 mg INDERAL LA once daily. The usual effective dose range is 160-240 mg once daily. The dosage may be increased gradually to achieve optimum migraine prophylaxis. If a satisfactory response is not obtained within four to six weeks after reaching the maximum dose, INDERAL LA therapy should be discontinued. It may be advisable to withdraw the drug gradually over a period of several weeks.

HYPERTROPHIC SUBAORTIC STENOSIS—80-160 mg INDERAL LA once daily.

PEDIATRIC DOSAGE—At this time the data on the use of the drug in this age group are too limited to permit adequate directions for use.

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HBP Commentary

Treatment of Hypertension in Special Populations

ELIJAH SAUNDERS MD

Dr. Saunders is Associate Professor and Head, Division of Hypertension, University of Maryland School of Medicine.

The 1984 Report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC III), which presents revised national guidelines, was reviewed in this *Journal*.[1,2] However, special populations and management problems, singled out in the Report for specific comment based in part on results of new studies either completed or in progress, have not been reviewed here. Treatment of these special groups, which include blacks; the elderly; hypertensives with diabetes mellitus, cerebral vascular disease, and coronary artery disease; surgical candidates; and the young, deserves comment.

Black Hypertensive Patients

The prevalence rate of hypertension in blacks in the United States is considerably higher than the rate in the white population, and hypertension-related deaths are disproportionately higher among black individuals. Vigorous detection, counseling, referral, and follow-up measures are particularly important in this group.[1]

Careful evaluation should be given patients falling into the following categories, even if blood pressures are elevated only modestly.

a) Black males less than age 50.
b) Blacks with family history of hypertension, especially if history reveals evidence of target organ damage or premature mortality associated with hypertension.
c) Blacks with diabetes mellitus, or who are heavy cigarette smokers, or have elevated serum lipids or other risk factors for atherosclerosis.

There is evidence that there is a higher rate of primary, or essential, hypertension in the black population than in the white; therefore, it is probably reasonable to suggest that an abbreviated work-up should be adequate for most black patients, rather than an extensive search for secondary causes. Since this costs less, it is more acceptable for this population. In addition, it encourages prompt institution of necessary therapy.

There is increasing evidence that, because of a suppressed renin system, along with probable volume expansion, beta-blockers and converting enzyme inhibitor drugs may not be as effective as single agents in blacks as compared to whites. Conversely, thiazide-type diuretics are much more likely to be effective as single agents in black hypertensives; in addition, they are much cheaper, an advantage for poorer individuals.

Elderly Hypertensive Patients

The elderly deserve additional comment both because of the frequency of hypertension in this age group and the lack of adequate data giving guidelines for treatment.

A significant proportion of the population older than 65 years of age has isolated systolic hypertension (systolic pressure ≥160 mm Hg; diastolic <90 mm Hg).[3] Additionally, many patients who have systolic and diastolic hypertension in their younger years will survive to add to the number of elderly hypertensive patients. Elevated systolic and/or diastolic blood pressure increases the risk of cardiovascular morbidity and mortality even in these elderly populations.

When diastolic hypertension appears *de novo* after the age of 60, a secondary cause, usually renovascular disease, should be suspected.

Data from the Hypertension Detection and Follow-up Program[4] indicate that elderly patients who have diastolic blood presssures ≥90 mm Hg (or ≥95 mm Hg in the Australian national trial, which did not specifically study patients with lower diastolic pressures)[5] will benefit from antihypertensive therapy. In the HDFP trial, patients 60 to 69 years of age at time of entry into the study had no more adverse drug reactions than younger patients and their adherence to drug regimens was just as good, if not better, than that of younger patients.

There are no data to confirm the efficacy of antihypertensive treatment in reducing the increased risk of cardiovascular disease associated with isolated systolic hypertension, even at high levels .... [A double-blind placebo controlled trial, Systolic Hypertension in the Elderly Program (SHEP) sponsored by NHLBI and the National Institute on Aging, was recently described in this *Journal*.][6] For elderly patients with isolated systolic hypertension, the decision to treat must be individualized.[1]

For most elderly patients with isolated systolic hypertension, instituting treatment with dietary sodium restriction and weight reduction, if necessary, seems warranted. If the decision is made to treat isolated systolic hypertension with drugs, the systolic pressure should be lowered cautiously to the goal of 140 to 160 mm Hg. If this level is well-tolerated, it is reasonable to attempt to reduce the systolic pressure below 140 mm Hg, as long as this can be accomplished without side effects.[1]

Practically all the therapeutic agents that have been found to be effective in younger persons also will be effective in older persons with isolated systolic hypertension, but the drug dosage should be reduced significantly. It is important to remember:

Elderly patients may be more sensitive to volume depletion and sympathetic inhibition than younger patients, because they frequently have impaired cardiovascular reflexes making them more susceptible to hypotension; for this reason, antihypertensive treatment should be initiated with smaller than usual dosages. Increases in dosage should be small and spaced at longer than usual intervals.[1]

HBP Commentary is contributed by the Maryland High Blood Pressure Commission, 201 W. Preston St., Baltimore, MD 21201 (301-383-7263). Editors: R. Patterson Russell MD, Past Chairman; Donald O. Fedder PharmBS, DrPH, Chairman; and Carol Lewis MPH, ScD, Executive Director.

Hypertensives with Diabetes Mellitus

Patients with hypertension and diabetes mellitus (DM) are particularly vulnerable to the cardiovascular complications of untreated hypertension, and diastolic pressure should be kept below 90 mm Hg by appropriate therapy.[1]

The combination of hypertension and DM is very common. It is estimated that almost half of diabetics are hypertensive. Therapeutic implications to be considered include the use of diuretics and beta-blockers, which may aggravate the blood sugar; beta-blockers also may mask catecholamine responses of hypoglycemia. While diuretics and beta-blockers are not contraindicated for use in diabetics, one should be aware of the possible biochemical and clinical aberrations.

Hypertension in Patients with Cerebrovascular Disease

Antihypertensive treatment reduces the incidence of initial and recurrent strokes in hypertensive patients; therefore, the presence of cerebrovascular disease does not contraindicate treatment of hypertension. The goal of therapy is to normalize blood pressure gradually, avoiding orthostatic hypotension.[1]

Hypertension in Patients with Coronary Artery Disease

Coronary artery disease is not a contraindication to the treatment of hypertension. As with patients having cerebrovascular disease, the elevated pressure should be reduced gradually to avoid hypotensive episodes. Beta-blockers may be specifically indicated because they decrease angina pectoris. In addition, for those who have had a myocardial infarction and who are, therefore, at greater risk of having another event, beta-blockade may prevent or delay subsequent myocardial infarction and reduce the risk of sudden death. Prolonged control of elevated pressure may prevent congestive heart failure and is associated with improved myocardial function. Furthermore, increased frequency of angina pectoris or myocardial infarction is not seen in patients with atherosclerotic heart disease when elevated pressures are carefully reduced to goal.[1]

Although elevations of blood lipids have been known to occur with use of some antihypertensive drugs (diuretics and beta-blockers), the clinical significance is presently unknown. Therefore, these drugs are strongly recommended, although the dosages of the diuretics should be kept at lower levels as recommended by the JNC III.

Hypertension in Surgical Patients

Previously the importance of gradually discontinuing drug therapy prior to surgery, in order to avoid rebound phenomena, was emphasized. However, it is now recommended that blood pressure be controlled up to the time of surgery; this may include the use of intravenous medication or oral medication with small amounts of water during the immediate preoperative period. The preoperative regimen should be restarted as soon as possible after surgery. Should rapid rebound hypertension occur following sudden discontinuation of various adrenergic-inhibiting agents, parenteral therapy can be provided. It seems clear that it is ill-advised to allow the blood pressure to exacerbate by withholding drug therapy during the preoperative period. In addition,

Adequate potassium supplementation should be provided to correct hypokalemia well in advance of surgery. A brief course of intravenous potassium just prior to surgery may not be sufficient to correct long-standing hypokalemia. In all cases, the anesthesiologist should be informed about the patient's medication status.[1]

Hypertension in the Young

Measurement of blood pressure should be standard practice in the health care of all children .... Whenever blood pressure measurements are obtained in children, attention should be given to correct equipment and technique. The widest cuff that will comfortably encircle the upper arm without covering the antecubital fossa should be used.[1]

Hypertension is relatively rare in children; when present, every effort should be made to identify a secondary form. It is important in this group to recognize the tremendous lability of blood pressure. Drug therapy should be delayed as long as possible, using nonpharmacologic approaches such as reduced caloric and sodium intake as the major therapeutic modalities. Other risk factors, such as lipid disturbances, must be assessed.

The National Heart, Lung and Blood Institute will soon make public its new guidelines for defining and treating pediatric hypertension; this column will give information on how to procure them.

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Medical Miscellany

AMA Survey and Opinion Briefs

Advertising in Medicine

As competition in the health care sector increases, issues related to the advertising of medical services and products are becoming more important. Proponents of competition in medicine as a solution to rising costs often stress the need for consumers to adequately understand medical products and services. From a marketing perspective, advertising is one of the most common ways of creating consumer awareness of medical services, especially if they are new.

Because of this issue's growing importance, the American Medical Association's 1984 public opinion survey examined consumer views toward advertising in two areas:

- proposals to allow pharmaceutical manufacturers to advertise prescription drugs on television directly to consumers, and
- awareness of advertising by hospitals and clinics in the recent past.

Prescription Drug Advertising to Consumers In February 1983, the Food and Drug Administration (FDA) asked the pharmaceutical industry to refrain from advertising prescription drugs directly to consumers. Since that request, several groups have called for an end to the moratorium on prescription drug advertising. However, because of many potentially negative consequences of such advertising, the debate continues. For this reason, a series of questions was included in the AMA's 1984 public opinion survey to measure consumer opinion on this issue.

Let's think about drugs that are available only with a doctor's prescription. Recently there has been discussion about allowing drug companies to advertise prescription drugs on television. Do you support or oppose prescription drug advertising on television?

	Public 1984
Support TV ads	34 percent
Oppose TV ads	62 percent

As indicated, the public opposes prescription drug advertising on television by a two-to-one margin. However, support varies substantially across different regions of the U.S. In the Pacific area (California, Washington, Oregon), only 27 per cent express support while 43 per cent of West South Central residents (Texas, Oklahoma, Arkansas, Louisiana) are in favor of drug advertising.

The survey then included an open-ended question:

Why do you (support/oppose) prescription drug advertising on television?

Reasons for Support	
More informed choice	25 percent
General consumer education	24 percent
Reasons for Opposition	
Negative effect on traditional MD role	6 percent
Leads to drug abuse	21 percent

The reasons given for support and opposition parallel arguments advanced in the national debate over this issue. The competitive model's stress on informed choice is strongly reflected as a reason for support. In contrast, interference with the traditional physician's role and the potential for increased drug abuse emerge as major concerns underlying opposition to this proposal.

Advertising by Hospitals and Clinics In an attempt to improve their market share, certain hospitals and clinics have begun to advertise their outpatient services. To determine the extent of this activity, public respondents were asked:

Have you seen or heard any advertising by hospitals or clinics during the past several months?

	Public 1984
Yes	41 percent
No	58 percent

The AMA's 1983 public opinion survey asked a similar question about advertising by physicians. Last year 28 per cent of the public reported seeing or hearing ads by physicians. In comparison, hospital or clinic advertising is more prevalent, but contact varies substantially among demographic subgroups.

Percent Seeing or Hearing Ads

Aged 18–34	45	Up to $10K income	31
Aged 65+	29	$30K+ income	54
Less than high school	20	Middle Atlantic region	27
College graduate	53	Pacific region	52

There are several factors, including differences in recall, that may account for these substantial differences by education, age, income and region. However, it is likely that hospital outpatient service and clinic facilities are targeting ads to young, up-scale, highly educated individuals in an effort to improve their market share in these groups. The strong regional differences also reflect, in large part, differences in the extent

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of general competition among providers of physicians' services in these areas.

These data from the AMA's 1984 public opinion survey indicate that:

- the American public is solidly against prescription drug advertising on television at this time, and
- contact with advertising by hospitals and clinics is prevalent, especially among young, well-educated, high income groups.

For further information, please contact Larry J. Freshnock, PhD, Director of Survey and Opinion Research (312) 645-4450.

• • •

WBAL-TV Offers Service to Health Professionals

WBAL-TV broadcasts a unique weekly series for physicians and health professionals. PHYSICIAN'S JOURNAL UPDATE, produced by Lifetime Medical Television, provides concise analyses of the week's important medical journal articles.

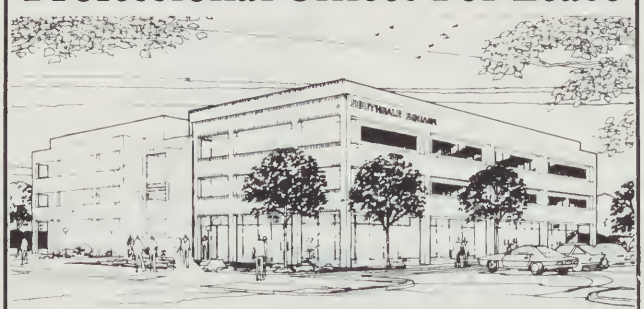
Each week more than sixty medical journals are reviewed by Lifetime's editorial board, distinguished physicians who select topics ranging from research breakthroughs and treatment trends to patient concerns and socioeconomic issues. PJU keeps busy physicians current and brings them face-to-face with individuals whose actions determine the course of today's medicine.

Lifetime Medical Television Chairman Dr. Art Ulene says of the award-winning program, "PJU has proved that good medicine can also be turned into good television." PJU was the first weekly program to be sanctioned by the Food and Drug Administration to carry prescription drug advertising. The FDA also recently approved distribution of PHYSICIAN'S JOURNAL UPDATE by broadcast television. The new arrangement will allow a greater number of health care professionals to view the program.

For greatest convenience PHYSICIAN'S JOURNAL UPDATE is broadcast each Saturday from 4–6 A.M. The early morning time allows the program to be videotaped and viewed by the individual as their schedule allows.

PJU has been distributed by satellite and Lifetime Cable, a joint venture of Hearst, ABC and Viacom. WBAL-TV is owned by the Hearst Corporation.

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Auxiliary

Kathleen Schimunek Karpers, the 1985–86 President of the Auxiliary, and her husband Bernard are both native Baltimoreans with deep roots in the Baltimore community. Kathy was born in the East Baltimore neighborhood of Canton where her father was a general practitioner for forty-five years. Kathy remembers that her mother has always been active in the Baltimore City Auxiliary. On the occasion of the second Annual Med-Chi Ball, which was organized by the Baltimore City Auxiliary, the young daughters of the city physicians were invited to be flower girls. As a youngster Kathy and her sister served as flower girls, and she recalls being asked to participate again the following year.

Kathy attended St. Brigid's elementary school, which is still educating Baltimore children and which her father had also attended. She went on to Notre Dame of Maryland Preparatory School, now located in Baltimore County, then on North Charles Street. Showing early leadership qualities, she served as class president, secretary, and treasurer in those organizations. She laid the groundwork for participation in athletics (which continues to the present) playing badminton, basketball, field hockey, and she swam.

Kathy graduated from the College of Notre Dame of Maryland, also located in Baltimore, with a B.A. in elementary education. Her first position was at the Commodore John Rogers School in Baltimore City. She especially loved to teach younger children.

She and Bernie first met when she was a college junior and he was a junior at the University of Maryland Medical School. An internist, Bernie graduated in 1962. He was a fellow in Biochemistry, a member of Alpha Omega Alpha, and he received the Medical Book Award for Scholastic Attainment. He frequently took time to give talks on health to Kathy's students.

They were married in 1963 in Baltimore at St. Brigid's Church and promptly moved to Columbus, Georgia, where Bernie served as Battalion Surgeon Second Infantry Division and Kathy became a leader in the Officers' Wives Club. They still enjoy visiting with former Army colleagues.

Returning to Baltimore, Bernie did his residency at University of Maryland Hospital, and Kathy returned to teaching first grade at Norwood Elementary School in Baltimore County. She was soon asked to be a Supervising Teacher and taught students from the College of Notre Dame of Maryland and Towson State. She also taught at Chase Elementary School. Bernie also continued with his health talks. Kathy cherishes her on-going friendship with many teachers and former students.

Bernie is a Board Certified internist practicing in Baltimore and active in both the Baltimore City Medical Society and Med-Chi. He has been secretary of the latter since 1977.

The Karpers established a home in Towson, and Kathy began participating in a variety of organizations. She served on the Board of the Lung Association of North Central Maryland for over five years, and chaired the Scholarship Committee. With the consolidation she is now on the Board of the American Lung Association of Maryland, Inc., and Kathy serves on the Grants and Awards Committee. She is a member of the Faculty Wives Association of the University of Maryland School of Medicine and has long been active in the Baltimore City Auxiliary, serving as President from 1977–79. Kathy has served the State Auxiliary as Health Careers, Convention and Membership Chairman and Secretary. She is now on the MMPAC Board. Kathy also participates actively in the Sodality of the Immaculate Heart of Mary Church and both her high school and college Notre Dame Alumnae Associations.

Despite all this she finds time for homemaking, cooking, boating, fishing, water skiing, gardening, and backyard badminton. She is a certified Red Cross Water Safety instructor and has taught swimming at summer programs for the YMCA.

Kathy Karpers is a many faceted woman, but family, nephews and nieces, and treasured friendships are central to her life. She especially enjoys holiday gatherings and family activities at their home.

Under Kathy's leadership our next Auxiliary year should be an especially warm and friendly one.

BARBARA M. MAYLE
Editor

Auxiliary to the Medical and Chirurgical Faculty of the State of Maryland. Mrs. Kathleen S. Karpers, President; Mrs. Barbara M. Mayle, Editor.

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Members in the News

Claude D. Hill MD recently was elected president of the medical staff of Bon Secours Hospital. He is certified by the American Board of Obstetrics and Gynecology and has been a member of the hospital staff for twenty-five years. He is a graduate of Meharry Medical College and received his residency training at Kansas City General Hospital, Kansas City, Missouri. Dr. Hill is a fellow in the American College of Obstetrics and Gynecology, and is a past president of the Obstetrical and Gynecological Society of Maryland.

• • •

Arthur T. Keefe MD has been named medical director of the newly consolidated Blue Cross and Blue Shield of Maryland, Inc.

As medical director of the corporation, Dr. Keefe is responsible for the development and implementation of corporate medical policies. He also serves as chairman of the Medical Relations and the References and Appeals committees. The former body advises the Board of Directors on medical policy while the latter arbitrates grievances concerning medical policy and the determination of benefits.

A graduate of Yale University and the Columbia College of Physicians and Surgeons, Dr. Keefe served on the Blue Shield Board of Directors from 1966 to 1980 when he became the Blue Shield medical director. Prior to joining the Blue Shield staff in 1980, he practiced general surgery at the Kent and Queen Anne's Hospital for 27 years.

Dr. Keefe is a diplomate of the American Board of Surgery, a fellow of the American College of Surgeons. He is secretary of the Maryland State Board of Medical Examiners and serves on the Board of Directors of the Maryland Center for Health Education.

• • •

Laura Jane Millicovsky MD has been appointed staff psychiatrist in the Adolescent Program at Taylor Manor Hospital, Ellicott City, Maryland. She has been placed in charge of the Girls Unit in Adolescent Services. Dr. Millicovsky joined the Hospital after leaving private practice in Plattsburg, New York.

Dr. Millicovsky is a member of the American Psychiatric Association, American Academy of Child and Adolescent Psychiatry and Alpha Omega Alpha. She received a fellowship in child and adolescent psychiatry at Western Psychiatric Institute and Clinics, University of Pittsburgh, Pennsylvania, after completing three years of general psychiatry residency at University of North Carolina.

The Maryland Chapter of the American Academy of Pediatrics awarded its highest honor, "Pediatrician of the Year" award, to **Thomas E. Reichelderfer** MD at its March 1985 Winter Meeting in Bethesda.

Dr. Reichelderfer received his medical degree in 1950 at the Johns Hopkins University and added to it a MPH degree in Public Health Administration (Child Welfare 1956). He served his pediatric internship at the Mary Hitchcock Memorial Hospital (Dartmouth Medical School) and the remainder of his pediatric residency at the Harriet Lane, ending as Chief Resident in 1953–54. He then had fellowships in maternal and child health in the United States Children's Bureau, the National Foundation for Infantile Paralysis, and the Johns Hopkins School of Public Health and Hygiene.

Dr. Reichelderfer is on staff at the Johns Hopkins Hospital as attending pediatrician.

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COMMISSION ON MEDICAL DISCIPLINE:
Dual Fee Schedule Opinion*

On February 19, 1985 you filed a Petition for Declaratory Ruling with the Commission on Medical Discipline of Maryland (the "Commission") on behalf of the Medical and Chirurgical Faculty of Maryland ("the Faculty") which requests the Commission to address the following issues related to the Commission's previously announced policy on dual fee schedules:

1. Whether a physican who does not participate in the Medicare program can raise his or her fees to non-Medicare patients without maintaining a "dual fee schedule."

2. Whether a physician can participate in a program that requires the physician to lower his or her fees to program members, without maintaining a "dual fee schedule."

3. Whether a physician can participate in a program that requires the physician to discount his or her fees to program members without maintaining a "dual fee schedule."

4. Whether a ruling that the above issues do not constitute "dual fee schedules" is consistent with Respondent's opinions concerning "dual fee schedules."

The decision to issue a declaratory ruling rests within the Commission's discretion. As a general rule the Commission restricts the issuance of such rulings to licensees who fall within the jurisdiction of the Commission. Although the Faculty itself is not within the jurisdiction of the Commission, it represents many licensees. Consequently, in order to give guidance to these licensees the Commission has decided to issue a declaratory ruling at the Faculty's request.

After reviewing the Petition and accompanying Memorandum and documents, the Commission has concluded that physicians should be able to enter into contractual arrangements with third party payors to provide services at a discounted rate to patients who participate in the third party payors' program. Furthermore, these physicians should be able to charge a different, higher rate to patients who do not participate in such programs. In reaching this conclusion the Commission was addressing new forms of reimbursement such as PPOs, HMOs, IPAs, and other types of insurance programs which require that participating physicians either discount or lower their fees to program members.

The Commission has also concluded that physicians who do not participate in the Medicare Program may raise the fees they charge non-Medicare patients if it is appropriate to do so. Under the Medicare rules which became effective in October, 1984 a non-participating physician may not increase fees charged to Medicare patients even though the physician has increased fees charged to non-Medicare patients for the same service.

The original dual fee policy was issued by the Commission at a time when the new forms of practice, described above, did not exist and before adoption of the new Medicare rules. That policy was based on the assumption that the purpose of a dual fee schedule is to obtain a fee above the physician's usual and customary fee charged to most patients from a payor (typically an insurance company) who the physician believes is able to pay the higher amount.

Underlying the prohibition is a recognition of the fact that the higher rate does not bear a reasonable relationship to the value of the service but is instead related to the availability of funds. In essence, the policy was adopted to prohibit a particular form of fraudulent billing and overcharging and presumed that any dual fee schedule of this type constituted immoral conduct in the practice of medicine. Although the policy does not specifically discuss the absence of knowledge or a contractual relationship between the physician and the payors, it is clear that deception and the lack of a legitimate basis for the dual fees was a major element in the policy statement.

Under the new forms of practice and the Medicare rules there is a legitimate basis for dual if not multiple fee schedules. A physician can at the same time participate in a number of insurance programs and be a non-participating physician who treats Medicare patients. That physician may also treat patients who are neither covered by the insurance programs nor are Medicare recipients and the fees charged these patients, while higher are still within the usual and customary fees charged. Under such circumstances, the maintenance of multiple fee schedules is not, in the opinion of the Commission, fraudulent or otherwise illegal. No one is "over charged."

Conclusion

It is, therefore, the decision of the Commission that the term "dual fee schedule" should be abolished because it does not accurately describe current reimbursement practices and its continued use will be misleading. Previous policy statements by the Commission on Medical Discipline regarding dual fee schedules are superseded by this declaratory ruling. Cases where a physician charges different fees for the same service depending on the identity of the payor will be reviewed on an individual basis. A physician who participates in an HMO, IPA, PPO, and other types of insurance/provider programs which require that participating physicians either discount or lower their fees to program

* In response to the Faculty's Petition for Declaratory Ruling, the Commission issued this ruling in letter form.

members, will not be viewed as engaging in a prohibited practice when charging one fee for program members and a different, higher fee for nonmembers. Similarly, non-participating physicians may, if appropriate, raise the fees charged to their non-Medicare patients. Obviously, all private patient rates should be consistent with the Federal Truth in Lending Act, be based on the time spent and complexity of the procedure administered, and be within the usual and customary range.

HILARY T. O'HERLIHY, MD, Chairman
Commission on Medical Discipline of Maryland
March 5, 1985



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Osteoarthritis VIII:—Surgical Management of the Knee

DENNIS W. LENNOX MD

Dr. Lennox is Assistant Professor, Department of Orthopaedic Surgery, Johns Hopkins University School of Medicine, Good Samaritan Professional Building, Baltimore, MD 21239.

Although for most patients with osteoarthritis of the knee the underlying etiology is unknown, previous knee injuries such as torn menisci, intra-articular fracture of the tibia or femur, tibial or femoral shaft fractures that result in angular deformity at the knee, and ligamentous injuries that produce instability of the knee often result in osteoarthritis.

For many, the symptoms of osteoarthritis can be controlled adequately with a combination of medications, physical therapy, intra-articular steroids, environmental modification, orthoses, and activity limitation. When these treatments fail to provide adequate pain relief and function, surgery may be indicated.

The knee joint may be considered to consist of three compartments or articulations: the medial tibiofemoral compartment, the lateral tibiofemoral compartment, and the patellofemoral compartment (Figures 1 and 2). Surgical treatment depends on the severity of involvement and on which compartments are involved.

When osteoarthritis is limited to the medial tibiofemoral compartment, varus or bowleg deformity results (Figure 3, next page). When disease is limited to the lateral tibiofemoral compartment, valgus or knock-knee deformity is evident (Figure 4, next page). Disease in the patellofemoral compartment narrows the patellofemoral joint and is readily visualized with special views of that joint obtained with the knee flexed and with the x-ray beam directed along the axis of the patellofemoral joint (Figure 5, next page). Quite often, particularly in the late stages of osteoarthritis of the knee, all three compartments are involved (Figures 6 and 7, page 465).

Surgical procedures for osteoarthritis of the knee include debridement, osteotomy, unicompartmental replacement, allograft, total knee arthroplasty, arthrodesis, and procedures for patellofemoral arthritis.

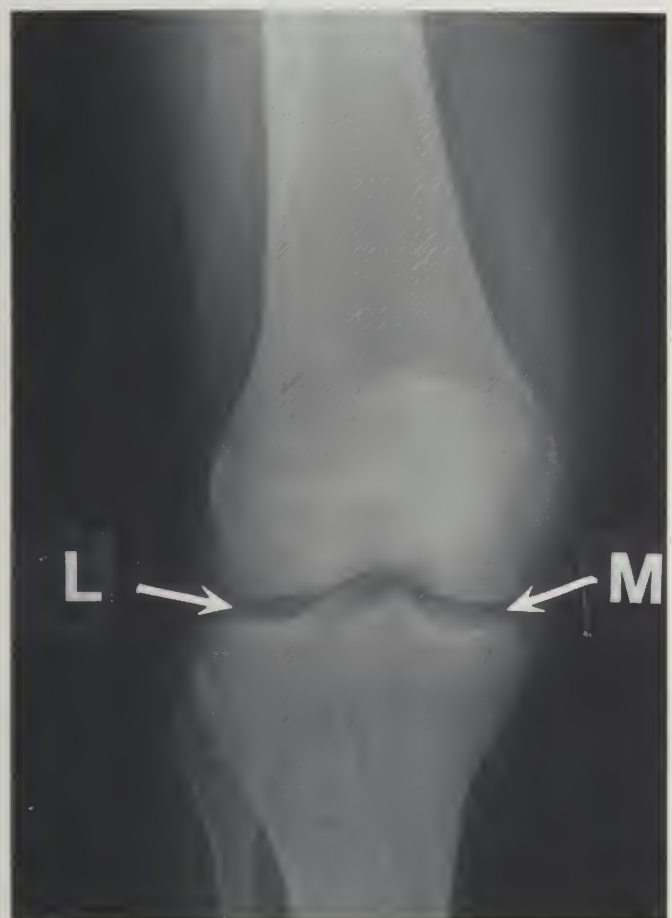


Figure 1. AP roentgenogram indicates medial (M) and lateral (L) tibiofemoral compartments of the knee.



Figure 2. Lateral view of the knee demonstrates patellofemoral joint (P.F.).



Figure 3. Narrowing of the medial tibiofemoral compartment creates varus (bowleg) deformity of the knee.



Figure 4. Lateral compartment narrowing creates valgus (knock-knee) deformity as in this left (L) knee.

Debridement

Debridement of the knee may be performed by arthrotomy or using arthroscopic surgery depending on the nature of the condition and the experience and preference of the surgeon. Debridement is usually applied to early or mild osteoarthritis of the knee and addresses a specific abnormality. Arthroscopic surgery offers the possible advantage of a rapid return to function with a shorter period of hospitalization than might be possible with arthrotomy. It is applicable to conditions such as torn menisci, the presence of loose osteocartilaginous bodies or, rarely, the removal of osteophytes that may impede motion or produce symptoms of pressing on soft tissue structures.

Osteotomy

Osteotomy of the proximal tibia or distal femur realigns the extremity and diminishes the stress on a degenerative compartment. Most commonly a tibial osteotomy is used to treat varus deformity (medial tibiofemoral joint osteoarthritis) (Figure 8, next page), and a distal femoral osteotomy is used to treat valgus deformity (lateral tibiofemoral osteoarthritis) (Figure 9, page 466).

Osteotomy works best for those patients with isolated medial or lateral tibiofemoral compartment disease, with a functional range of motion, good pulses and venous return, and without gross ligamentous instability.

Unicompartmental Knee Replacement

In unicompartmental knee replacement, the medial or lateral tibiofemoral joint is replaced with a metal component on the femoral side and with a polyethylene component on the tibial side (Figure 10, page 466). This procedure is applied when one knee compartment is involved and is used for the older patient with passively correctable deformity or for the relatively young individual with marked bone loss. Possible advantages of a unicompartmental knee replacement are rapid recovery

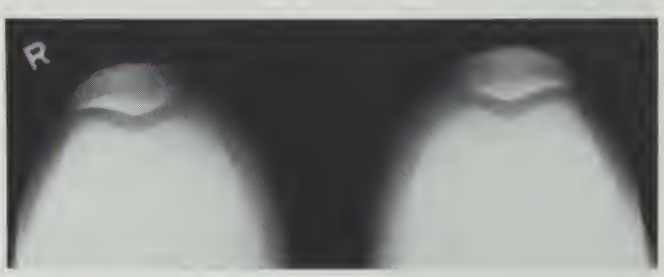


Figure 5. Patellofemoral view demonstrates clearly the patellofemoral joint.

and minimal blood loss. Loosening of the tibial component has been a problem with this procedure, but a new generation of prostheses that use cementless fixation are now being tested and may represent a significant improvement over the earlier devices.

Allograft

The use of small-fragment fresh allografts for the treatment of unicompartmental osteoarthritis has been proposed recently.[1] In this report severe unicompartmental osteoarthritis in patients younger than 50 years old was treated by osteotomy followed 9 to 12 months later by allografts in those who remained symptomatic. Allografts were implanted at the distal femur and proximal tibia in all patients. With an average follow-up period of 48 months, results with this new technique were quite variable, with 17 of 37 patients requiring additional surgery in the form of either transplant revision (1); revision and osteotomy (3); osteotomy (8); total knee arthroplasty (9); arthrodesis (2); and graft excision or debridement (3). Although the results with this method are variable at present, it represents an exciting area of investigation and may prove to be a popular technique when the clinical results are more consistently good and excellent. At this time, however, the use of allografts for the treatment of unicompartmental osteoarthritis must be considered a technique in an early phase of development.

Total Knee Arthroplasty

For patients with osteoarthritis of the knee with severe deformity, particularly when associated with marked deficiency of bone, total knee arthroplasty is the procedure of choice. Although for many years total hip arthroplasty was considered to be a more predictably successful and technologically advanced procedure than total knee arthroplasty, numerous advances in surgical technique and implant design have made total knee arthroplasty a frequently performed and rewarding procedure. Experts estimate that in the United States in 1985, approximately 100,000 total hip arthroplasties and 80,000 total knee arthroplasties will be performed.

Some of the early disappointing results with total knee arthroplasty were related to the prosthetic design. It is apparent the early total knee prostheses that used a hinge-type joint failed miserably because those prostheses applied huge forces to the interface between bone and polymethylmethacrylate cement (Figures 11 and 12, pages 466, 467). Loosening and failure with highly constrained prostheses were extremely common.



Figure 6. Both tibiofemoral compartments evidence severe osteoarthritis.



Figure 7. Patellofemoral view indicates moderate narrowing on the left (L).



Figure 8. High tibial osteotomy has been performed for medial compartment osteoarthritis.



Figure 9. Distal femoral osteotomy was used to treat valgus deformity in this knee.



Figure 10. Unicompartmental knee replacement.

Although hinged prostheses still are used occasionally, most surgeons limit the use of these devices to cases that because of global instability or marked bone loss could not otherwise be managed.

In total knee arthroplasty, the arthritic distal femur is replaced with a metallic component and the proximal tibial surface is replaced with a high molecular weight polyethylene component (often metal backed). Although traditional methods of fixation included the use of polymethlymethacrylate bone cement, a new generation of prostheses is based upon the concept of cementless fixation. Long-term results are needed to assess the possible benefit of cementless fixation, but early results have been encouraging (Figure 13 and 14, next page).

Indications for total knee arthroplasty include severe deformity and the presence of severe tricompartmental osteoarthritis (Figure 15, page 468). Another factor to be considered in total knee arthroplasty is the age of



Figure 11. A cemented hinged knee replacement has been inserted. Methylmethacrylate bone cement is visualized as a radio-opaque material surrounding the prosthetic component. Loosening has occurred.

the patient. Total knee arthroplasty is more likely to be used in elderly patients since it offers a more rapid return to activity than osteotomy as well as good immediate results. Older patients tend to be less active and thus aseptic loosening of total knee arthroplasties is a lesser problem in the older groups than in a younger, more active patient population.

Arthrodesis

Arthrodesis (fusion) of the knee is used quite infrequently and is applied to a number of specific conditions. Most commonly, arthrodesis is used as a salvage operation in cases of osteoarthritis following knee infection or failed total knee replacement. Other situations to which fusion may apply include the young adult with posttraumatic osteoarthritis, cases of neuropathic arthropathy, or osteoarthritis in a flail lower extremity (Figure 16, page 468).

Patellofemoral Joint Procedures

A number of surgical procedures have been applied to treat isolated osteoarthritis of the patellofemoral joint. This disorder often is associated with previous patellar trauma (including fractures), patellar dislocation, or subluxation.

Chondroplasty Although shaving of the undersurface of the patella has been advocated by some, the results with this technique are highly variable.

Retinacular Release, Realignment Recurrent patellar subluxation may be treated by a lateral retinacular release with improvement in symptoms. Realignment of the quadriceps mechanism by soft tissue reconstruction or transposition of the patellar tendon may provide relief in some cases of subluxation.

Tibial Tubercle Elevation Where roentgenographic evidence for patellofemoral arthritis exists, that is, documented joint space narrowing best visualized on the patellofemoral views, elevation of the tibial tubercle often can provide symptomatic improvement. With this method the patellar tendon insertion at the tibial tubercle is elevated anteriorly.[2] This elevation diminishes the patellofemoral joint force and can provide pain relief by that mechanism.

Patellectomy For end-stage patellofemoral arthritis, patellectomy may be considered. This procedure can provide symptomatic relief but carries the disadvantage of reducing the effectiveness and mechanical advantage of the quadriceps mechanism. Patellectomy is considered by most to represent a salvage procedure in patellofemoral arthritis and is used infrequently.



Figure 12. Lateral view of loosened hinged prosthesis.



Figure 13. Cementless knee arthroplasty AP view.

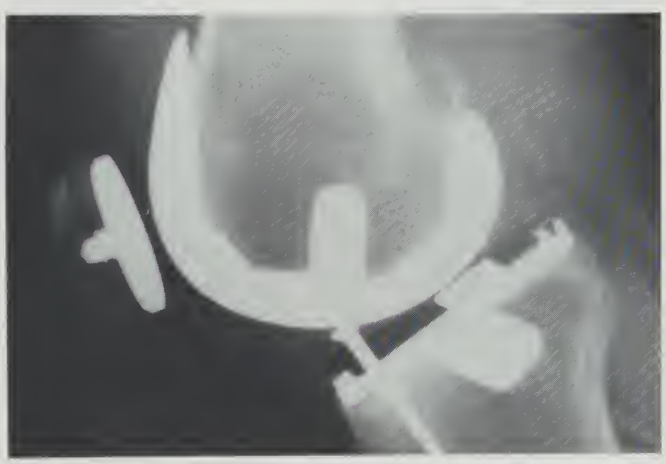


Figure 14. Cementless knee arthroplasty lateral view.



Figure 15. Lateral roentgenogram demonstrates severe tricompartmental involvement.



Figure 16. Knee arthrodesis AP view.

Summary

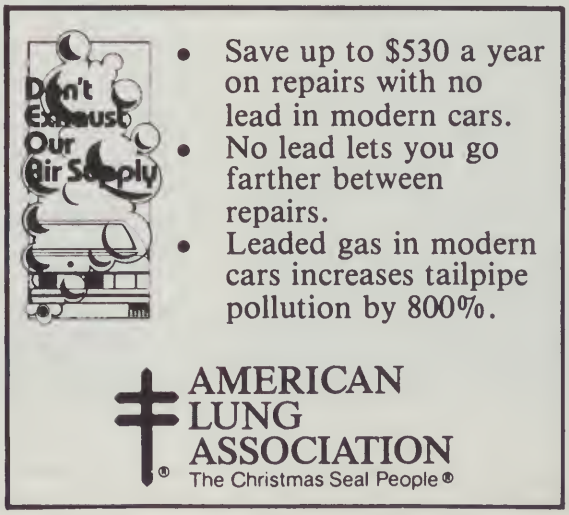
Osteoarthritis of the knee is a common disorder. When isolated medial or lateral tibiofemoral osteoarthritis exists, osteotomy of the distal femur or proximal tibia can provide pain relief through realignment of the limb and improved biomechanics. Early involvement may respond to debridement, possibly through arthroscopic surgery. Conditions associated with osteoarthritis of the knee which may be successfully treated with this method include torn menisci, loose bodies or osteophytes.

Another option for treating unicompartmental disease is unicompartmental knee replacement. The relatively new technique of allograft insertion to treat osteoarthritis is a promising area of ongoing investigation, but this method has been applied on a limited basis with highly variable results. Total knee arthroplasty is a widely accepted and successful technique for treating tricompartmental osteoarthritis. Advances in prosthetic design and biomaterials have improved this procedure immensely. Arthrodesis (fusion) can provide a pain-free, stable knee in cases of osteoarthritis after knee infection. Patellofemoral osteoarthritis may be successfully managed by tibial tubercleplasty or, rarely, by patellectomy.

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2. Ferguson, A. B.; Jr.; Brown, T. P.; Fu, F. H.; et al. "Relief of Patellofemoral Contact Stress by Anterior Displacement of the Tibial Tubercle." *J Bone Joint Surg* 61A (1979):159.



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Note: Culture and susceptibility tests should be initiated prior to and during therapy.

CONTRAINDICATIONS: In patients with known hypersensitivity to the cephalosporin group of antibiotics.

WARNINGS: *Use cephalosporin derivatives with great caution in penicillin-sensitive patients since there is clinical and laboratory evidence of partial cross-allergenicity of the two groups of antibiotics; there are instances of reactions to both drug classes (including anaphylaxis after parenteral use).* In persons who have demonstrated some form of allergy, particularly to drugs, use antibiotics, including cephradine, cautiously and only when absolutely necessary.

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PRECAUTIONS: General: Follow patients carefully to detect any side effects or unusual manifestations of drug idiosyncrasy. If a hypersensitivity reaction occurs, discontinue the drug and treat the patient with the usual agents, e.g., pressor amines, antihistamines, or corticosteroids. Administer cephradine with caution in the presence of markedly impaired renal function. In patients with known or suspected renal impairment, make careful clinical observation and appropriate laboratory studies prior to and during therapy as cephradine accumulates in the serum and tissues. See package insert for information on treatment of patients with impaired renal function. Prescribe cephradine with caution in individuals with a history of gastrointestinal disease, particularly colitis. Prolonged use of antibiotics may promote the overgrowth of nonsusceptible organisms. Take appropriate measures should superinfection occur during therapy. Indicated surgical procedures should be performed in conjunction with antibiotic therapy.

Information for Patients: Caution diabetic patients that false results may occur with urine glucose tests (see PRECAUTIONS, Drug/Laboratory Test Interactions). Advise the patient to comply with the full course of therapy even if he begins to feel better and to take a missed dose as soon as possible. Tell the patient he may take this medication with food or milk since G.I. upset may be a factor in compliance with the dosage regimen. The patient should report current use of any medicines and should be cautioned not to take other medications unless the physician knows and approves of their use (see PRECAUTIONS, Drug Interactions).

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Pediatric Use: Adequate information is unavailable on the efficacy of b.i.d. regimens in children under nine months of age.

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DOSAGE: Adults — For respiratory tract infections (other than lobar pneumonia) and skin and skin structure infections: 250 mg q. 6 h or 500 mg q. 12 h. For lobar pneumonia: 500 mg q. 6 h or 1 g q. 12 h. For uncomplicated urinary tract infections: 500 mg q. 12 h; for more serious UTI, including prostatitis, 500 mg q. 6 h or 1 g q. 12 h. Severe or chronic infections may require larger doses (up to 1 g q. 6 h). For dosage recommendations in patients with impaired renal function, consult package insert.

Children over 9 months of age — 25 to 50 mg/kg/day in equally divided doses q. 6 or 12 h. For otitis media due to *H. influenzae*: 75 to 100 mg/kg/day in equally divided doses q. 6 or 12 h but not to exceed 4 g/day. Dosage for children should not exceed dosage recommended for adults. There are no adequate data available on efficacy of b.i.d. regimens in children under 9 months of age.

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Preventive Cardiology

KAREN KUEHL MD

Studies suggest that atherosclerotic heart disease has a chronic pathogenesis and that preventive efforts should begin early in life.

Dr. Kuehl is Associate Cardiologist, Children's Hospital National Medical Center, 111 Michigan Avenue, NW, Washington, DC 20010.

Over the past 15 years, encouraging reductions have occurred in the rate of fatal heart attack and stroke in the United States. The cause of these reductions in death rates remains unclear. Despite these changes, atherosclerosis remains the leading cause of death in this country. Preventive medicine only recently has begun to address the problem of prevention of chronic diseases such as atherosclerosis.

The International Atherosclerosis Project studied the distribution of fatty deposits and raised intimal atherosclerotic lesions in multiple international populations and found evidence of extensive atherosclerosis in the third and fourth decades in individuals from countries with high rates of coronary artery disease.[1] This suggests that atherosclerotic heart disease has a chronic pathogenesis and that preventive efforts should begin early in life. Studies of U.S. soldiers who died in the Korean and Vietnam conflicts confirmed a prevalence of coronary artery involvement by atherosclerosis in young men.[2,3]

Risk Factors

The Framingham Heart Study defined characteristics that prospectively identified those individuals with increased likelihood of developing coronary artery disease or stroke over a period of ten to twenty years' observation. The major risk factors (as these characteristics are now termed) are hypercholesterolemia, hypertension, and cigarette smoking. Further analysis revealed that high levels of low density lipoprotein (LDL) cholesterol and low levels of high density lipoprotein (HDL) cholesterol are better predictors of coronary artery disease than is the total cholesterol level. Less potent risk factors include family history of coronary artery disease, type A behavior pattern, diabetes mellitus, and sedentary behaviors.[4]

Before initiation of efforts to prevent coronary artery disease by modification of childhood behaviors or risk-factor parameters, three questions needed to be answered. First, normative data for risk-factor parameters for children have been lacking until recently.[5,6] Second, risk-factor characteristics of children needed to be determined consistent at least throughout the childhood years. Third, demonstration that reduction in risk factor levels would prevent coronary heart disease has been convincingly provided only recently. The Lipid Research Clinics data showed that reduction of coronary heart disease death and nonfatal infarction were significantly correlated with reduction in LDL cholesterol achieved by administration of ion exchange resin to hypercholesterolemic adults.[7] Similar reduction of cholesterol started in childhood would be at least equally effective in preventing the development of atherosclerotic heart disease.

Prevention

Preventive cardiology can take either of two approaches. The first approach is directed toward modification of behavior in an entire population without identifying different or specific levels of risk factors in individuals. This position is well addressed in Rationale of the Diet Heart Statement of the American Heart Association.[8,9] A second approach, perhaps more appropriate to the practice of pediatric medicine, is to identify individuals at particularly high risk and to target interventions to that population. In this approach, monitoring of individuals to determine whether changes in risk factors have occurred with interventions permits alteration of interventions until the desired change is achieved. Thus, the Bethesda Conference on Prevention of Coronary Heart Disease recommended screening children from families with history of coronary heart disease occurring before age 60 years.[10]

Screening measurements of lipids should include determinations of cholesterol and triglyceride on fasted samples of blood, in duplicate. If the measurements are above the 95 percentile for age, sex, and race, determination of lipoprotein levels on a separate sample should be obtained. The coefficient of variation of total cholesterol is 3.9 percent and of triglyceride 25.9 percent, necessitating multiple measurements.[11] Colorimetric determinations of total cholesterol, which many physicians use for office screening procedures, give results significantly higher than the values derived from enzymatic analysis; thus, these screening methods should be confirmed prior to initiation of therapy.

Screening for risk of coronary artery disease should include determination of lipoprotein levels since low density lipoprotein cholesterol shows a strong positive and high density lipoprotein cholesterol a strong negative correlation with development of atherosclerosis. Practically, lipoprotein levels are estimated by measurement of total cholesterol, triglyceride, and high density lipoprotein cholesterol. The same enzymatic method should be used for both total cholesterol and HDL cholesterol determinations. Normolipemic very low density lipoprotein particles contain about 75 per-

cent by weight of triglyceride and about 15 percent by weight of cholesterol. Thus, the very low density lipoprotein cholesterol level can be estimated as 20 percent of the triglyceride value in mg/dl.

The total cholesterol in plasma is the sum of that in very low density, low density, and high density lipoproteins. The low density lipoprotein level can be estimated by subtracting from the total cholesterol level the value measured as high density lipoprotein cholesterol and the value estimated for very low density lipoprotein cholesterol. For example, if a boy has a total cholesterol of 210 mg/dl, triglycerides of 120 mg/dl, and a measured HDL cholesterol of 65 mg/dl, his estimated LDL cholesterol = 210 - 120/5 - 65 or 210-24-65 of 121 mg/dl, a high normal value.

Normal values for children from ages 5 to 19 are available by age, race, and sex specific subgroups from screenings carried out by the Lipid Research Clinics program. These normal values include total cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol.[12] These values for cholesterol are comparable only to patient samples analyzed in the same way. Over the broad age range 5 to 19 years, the 95 percentile for total cholesterol approximates 200 mg/dl for white children and is slightly higher (205 to 210 mg/dl) for black children, consistent with a higher mean level of HDL cholesterol in black children. Lipoprotein values show reasonable tracking or maintenance of relative rank over time. In children whose LDL cholesterol is above the 90 percentile on one determination, 87 percent will have LDL cholesterol above the 70 percentile on a second determination two years later.[13] As in adults, clustering of risk factors occurs in children, particularly in later childhood.[14] Thus, it is important that analysis of blood pressure, lipoprotein levels, exercise habits, and smoking behavior occur concurrently in children and that a multifactorial program be developed to modify all relevant behaviors in a coordinated way.

When a child is identified as hyperlipoproteinemic, other risk factors should be assessed as noted above. Assessment of renal, hepatic, and thyroid function should be made and a history of oral contraceptive or alcohol use should be sought to rule out secondary hyperlipoproteinemia.

Intervention

Interventions for the hyperlipoproteinemic child begin with dietary modification using the diets proposed by the American Heart Association for lowering cholesterol in hypercholesterolemic adults.[15] A first principle is to achieve lean body weight by appropriate reduction in calories and increase in exercise. However, most children seen with isolated hypercholesterolemia are not obese. The dietary interventions are divided in three stages.

Phase I: 30 percent of total calories as fat, 55 percent as carbohydrate, and 15 percent as protein. Cholesterol intake should be below 300 mg/day for adults.

Phase II: The percentage of total calories from fats is reduced to 25 percent and the cholesterol intake to 200 to 250 mg/day for adults.

Phase III: The percentage of total calories from fats is reduced to 20 percent and the cholesterol intake to 100 to 150 mg/day for adults.

In all phases it is recommended that the percentage of calories from protein remain at 15 percent with the remainder made up by increasing amounts of carbohydrates, particularly complex carbohydrates and those rich in soluble fiber and pectin. In all three phases it is recommended that the proportion of calories from saturated, monounsaturated, and polyunsaturated fats be equally divided, so that calories from polyunsaturated fats never exceed 10 percent.

Three to six hours of nutritional counseling are necessary to teach a family to shop, cook, and prepare menus of cholesterol-lowering diets. Group sessions using slide presentations, cooking demonstrations, and shared meals have been an effective way of achieving education at lowered cost per family. Repeat determination of lipoproteins, three-day diet history recording and analysis, and weight are followed every three months until LDL levels are within the 90 percentile. Telephone consultation with a nutritionist is available to patients throughout their follow-up.

In adults, cholesterol lowering by treatment with ion exchange resin clearly is effective in reducing mortality and incidence of coronary heart disease. Use of ion exchange resin in childhood for cholesterol lowering is appropriate in the homozygous child with familial hypercholesterolemia and often will be necessary to achieve significant cholesterol lowering in the teenager with heterozygous familial hypercholesterolemia despite maximal dietary compliance.

The practicing pediatrician is more familiar with blood pressure determination and treatment of hypertension than with hyperlipidemia; thus, emphasis in this article has been on lipids. Blood pressure determination annually over age three has been recommended for all children.[16] Blood pressure determinations in duplicate on three occasions are considered an adequate sample for assessment of hypertension.

Normative data for blood pressure in children are derived from screening surveys and are higher than basal blood pressures derived from the Bogalusa study.[17,18] Choice of normal data should reflect the

method the pediatrician is using to collect patient data. If elevated blood pressure is identified, electrolytes, blood urea nitrogen, creatinine, urinalysis, thyroid function, and leg blood pressures with examination are needed to rule out specifically treatable causes of hypertension. Initial efforts at blood pressure control in the moderately hypertensive child (particularly with family history of hypertension) focus on dietary intervention with respect to calories and sodium intake. Limitation of salt intake to 5 g NaCl daily (86 mEq Na) is easily achieved by removal of obviously salty foods and by adding no salt at the table. Ambulatory blood pressure monitoring and stress testing are useful adjuncts to assess the chronicity and magnitude of hypertension in children with modest blood pressure elevations.

Physicians by example and advice should be part of a continuing antismoking campaign for all children, not just those from high risk families. Physicians should monitor patients' smoking habits and advise against smoking at office visits as well as referring to (or maintaining) smoking-cessation programs for children who begin to smoke.[19]

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The Newborn with Acyanotic Congenital Heart Disease: Recognition and Management

LOWELL W. PERRY MD

The approach to acyanotic congenital heart disease in an infant should be systematic. If the infant is asymptomatic, observation is in order. However, if heart failure develops, complete evaluation and cardiac surgery may be indicated. Evaluation of the infant is enhanced by knowledge of the most common congenital lesions and their most likely age of manifestation.

Dr. Perry is Associate Cardiologist, Childen's Hospital National Medical Center; Professor of Child Health and Development, George Washington University School of Medicine, Washington, DC.

Cardiovascular disease in the newborn is suggested by a significant murmur, cyanosis, heart failure, or the physical appearance of the patient (for example, the patient with Down's syndrome). Since request for evaluation of the infant generally is not because of a specific known diagnosis, a logical sequential evaluation should be followed.

Initial Evaluation

The most common reason for suspecting heart disease is presence of a murmur. The first question to be answered when evaluating the infant with a murmur is whether cyanosis and/or heart failure are present. If neither is present, the patient generally can be observed and evaluation can proceed at a nonemergency pace. However, when cyanosis or heart failure is present, cardiology evaluation and additional studies are necessary.

Auscultation of the newborn presents several technical problems. The chest is small. All murmurs in newborns seem to be located over the lower left sternal border. The heart rate is rapid. It is difficult to determine whether murmurs are systolic or diastolic, regurgitant or ejection. Hence, all murmurs in the newborn may sound similar.

Using the largest stethoscope available will allow maximal appreciation of sound. No transmission suggests a ventricular septal defect or tricuspid regurgitation; transmission to back suggests pulmonary stenosis or patent ductus arteriosus; transmission to neck suggests aortic stenosis. Ascertaining whether a murmur is regurgitant or ejection requires comparison with many infants with rapid heart rates. Palpation of brachial pulse during auscultation helps separate systole from diastole.

In the patient with heart failure, it is helpful to be aware of possible etiologic factors. Congestive heart failure at birth may be cardiac or extracardiac. The first seven causes of heart failure at birth (Table 1) have in common right heart failure; thus, all have hepatic enlargement and most have edema.

If the infant develops heart failure during the first week of life, the etiology also may be cardiac or extracardiac. The cardiac causes of failure are somewhat different than those producing heart failure at birth (Table 2).

The cardiac causes of heart failure from one week to one month and from one to three months are in Table 3, next page. Beyond one week, heart failure developing

Table 1. Heart Failure at Birth

Cardiac Causes
AV malformations: cerebral, hepatic, renal, placental
Hypoplastic left heart: aortic and/or mitral atresia
Pulmonary stenosis or atresia with intact ventricular septum
Pulmonary valve insufficiency
Congenital tricuspid valve regurgitation
Ebstein's malformation of tricuspid valve
Premature closure of foramen ovale
Endocardial Fibroelastosis/cardiomyopathy/arrhythmia
Extracardiac Causes
Hemolytic diseases: anemia
Hyperviscosity or increased blood volume
Asphyxia: hypoxic cardiomyopathy

Table 2. Heart Failure During the First Week of Life

Cardiac Causes
Hypoplastic left heart
Complete transposition of great vessels
Total anomalous pulmonary venous return
Coarctation of aorta
Arrhythmia
Rare: endocardial fibroelastosis
rhabdomyoma of left ventricle
Extracardiac Causes
Pulmonary:
hypoxia
acidosis
respiratory distresss syndrome
pneumonia
atelectasis
pulmonary hemorrhage
choanal atresia
tracheomalacia
Sepsis:
myocarditis
meningitis
Renal disease:
cystic disease of kidney
hydroenphrosis
renal agenesis-produce metabolic acidosis
fluid overload
Endocrine:
hyperthyroidism

Table 3. Congestive Heart Failure

Age: One Week to One Month
Transposition of great vessels
Coarctation of aorta
Patent ductus arteriosus or aortopulmonary window
Truncus arteriosus
Myocarditis
Glycogen storage disease
Age: One Month to Three Months
Vascular septal defect
Patent ductus arteriosus
Atrioventricular canal defects

secondary to lesions associated with large left-to-right shunts is encountered.

Common Congenital Lesions

Of the lesions presenting in the newborn, 25 percent are acyanotic associated with obstruction and 40 percent are acyanotic associated with left-to-right shunts. The most common obstructive lesions are pulmonary stenosis, aortic stenosis, and coarctation of the aorta. Shunt lesions are ventricular septal defect, atrial septal defect, and patent ductus arteriosus.

Obstructive Lesions Pulmonary stenosis (PS) may be valvar, subvalvar, or branch. The hallmark is an ejection systolic murmur at the upper left sternal border with transmission to the back. An ejection sound that varies with respiration suggests valvar pulmonary stenosis. Increasing severity of PS is reflected by development of right ventricular hypertrophy on the electrocardiogram. If the lesion is mild, it most likely will remain mild; if it is severe or progressive, surgical treatment or interventional catheterization may be required. Generally, relief of obstruction is indicated if right ventricular systolic pressure is greater than 75 percent of systemic systolic pressure.

Aortic stenosis (AS) may be valvar, subvalvar, or supravalvar. Valvar aortic stenosis may be associated with an ejection sound. A murmur is ejection type and transmitted to the neck. A mild lesion (no left ventricular hypertrophy by electrocardiogram or echocardiogram and no significant gradient by Doppler echocardiogram) is followed medically; catheterization is indicated for a severe lesion. Surgery generally is recommended when the gradient across the aortic valve is 75 mm Hg or greater.

Coarctation of the aorta (CoAo) frequently is located in the vicinity of the ductus arteriosus. Hence, femoral pulses may be present until the ductus closes. CoAo is associated with blood pressure differential between arms and legs and diminished femoral pulses. The lesion commonly is associated with a bicuspid aortic valve; thus, an ejection sound and/or aortic outflow murmur may be present. If the lesion is associated with significant upper extremity hypertension or with persistent heart failure, early repair may be required. However, repair of uncomplicated coarctation of aorta should be postponed, if possible, until the patient is three to five years of age to minimize the risk of recurrence and persistent systemic hypertension. CoAo often exists with other anomalies (for example, ventricular septal defect) that may require early repair.

Shunt Lesions Pulmonary vascular resistance is increased in utero because there is no need for blood to flow to the lungs. At birth, pulmonary artery lumen size increases and pulmonary resistance and pressure fall. Flow in a vessel is directly related to pressure and inversely related to resistance to flow. Following birth, there is replacement of alveolar fluid by air, vasodilatation of the pulmonary arteries, and blood flow to the lungs. The ductus arteriosus closes.

The shunt lesions generally do not present problems in the newborn period. Left-to-right shunt is defined as a passage of oxygenated blood from the left atrium, left ventricle, or aorta to a right-sided chamber or vessel. In the presence of a ventricular septal defect, the amount of shunt from left ventricle to right ventricle is related to size of defect, pulmonary vascular resistance, and systemic vascular resistance. Given a large ventricular septal defect, the amount of pulmonary flow is related primarily to the pulmonary vascular resistance. If the pulmonary vascular resistance is less, the pulmonary flow will be greater.

With a ventricular septal defect at birth, the pulmonary vascular resistance is high; after the resistance decreases during the first days or weeks of life, clinical evidence of the ventricular septal defect may be evident.

The ventricular septal defect murmur is pansystolic, located over the lower left sternal border and not transmitted to neck or back. With a large shunt, increased loudness of the second heart sound and an apical middiastolic rumble may be present. Tachycardia, tachypnea, and cardiomegaly also are present with a large shunt.

There are four types of ventricular septal defect: membranous (the most common), supracristal, muscular, and posterior (AV canal type). The exact type is not important in early management; net effect on the patient is the primary concern. Up to 50 percent of small ventricular septal defects with no evidence of pulmonary hypertension close spontaneously by the end of the first year; up to 80 percent close by the tenth year of age. Only about 10 percent ultimately require surgery.

Surgical intervention is indicated if the patient fails to thrive, shows evidence of progressive elevation of pulmonary vascular resistance, or if persistent heart failure develops. If the child does well, yet has a large left-to-right shunt with flow to the lungs twice or more the flow to the body, elective surgical repair is recommended at three to five years of age. Surgery also is recommended if the patient develops aortic insufficiency, which may occur because of the proximity of the aortic valve to the supracristal or membranous defect.

Atrial septal defects generally have no clinical manifestations in the newborn and usually are diagnosed

between two and five years of age. Clinical manifestations of an atrial septal defect are a grade one to three ejection systolic murmur in the second left interspace with transmission to the back, a tricuspid diastolic flow rumble, fixed splitting on second heart sound, and increased right ventricular activity on palpation of the chest.

There are four types of atrial septal defect. The most common, secundum, is located in the middle of the septum. Ostium primum (or incomplete) type of endocardial cushion defect is located low in the septum and usually is associated with cleft mitral valve and left axis deviation on electrocardiogram. Sinus venosus defect is located superiorly and is associated commonly with partial anomalous pulmonary venous return. Single atrium, the least common of atrial defects, can be thought of as a large ostium primum defect since it is accompanied by cleft mitral valve and left axis deviation. Of secundum atrial defects 10 to 50 percent may undergo spontaneous closure.

Endocardial cushion defects of the complete type (also known as complete type of atrioventricular canal defects) are physiologically combinations of both atrial and ventricular septal defects. These defects often are associated with Down's syndrome. They may present with nonspecific murmur and left axis deviation. The presence of heart failure depends on the status of pulmonary vascular resistance. Diagnosis is supported by echocardiography. If heart failure is controlled and there is no evidence of progressive pulmonary vascular disease, surgical repair is recommended when the child is about one year old.

Heart Failure

Congestive heart failure is associated clinically with cardiomegaly, hepatomegaly, tachypnea, tachycardia, gallop rhythm, and edema. On chest film the heart is enlarged and there is pulmonary congestion. The echocardiogram may be nonspecific but demonstrate diminished contractility, chamber dilatation, or hypoplasia and give specific clues as to the anatomic abnormality. Depending on the severity of the failure there may be acidosis, respiratory or metabolic, increased arteriovenous oxygen difference, dilutional hyponatremia, and hypochloremia. Hemoglobin may be decreased due to fluid retention. Albuminuria, increased specific gravity, and microscopic hematuria may be present on urinalysis. Hypoglycemia and hypocalcemia may be present.

Digitalis remains the cornerstone to treatment of heart failure. Verifying calculated dosage with an independent observer is recommended. Dopamine, isoproterenol, epinephrine, and other ionotrophic agents may be used when severe heart failure is accompanied by renal failure. Diuretics are administered to improve renal function. Peripheral vasodilators are used to decrease systemic vascular resistance.

The infant with heart failure often is more comfortable in a sitting position. Oxygen may be helpful, but it is a potent pulmonary vasodilator; the infant with ventricular septal defect or endocardial cushion defect might do better in room air than in atmosphere enriched with oxygen. Severe respiratory distress may require respirator support. Antibiotics should be used if there is any question of infection. Morphine may be useful in the presence of pulmonary edema.

Diet is important for the infant with heart failure. Caloric intake of at least 120 calories per kg is required for growth. Nasogastric or gastrostomy feedings may be necessary.

Once heart failure has stabilized, additional evaluation (usually including cardiac catheterization) is needed to plan logical treatment of underlying cardiovascular malformation.

Counseling

In counseling parents of a child with heart failure, it is important to stress the following points even when the exact diagnosis is unknown: (1) Heart failure is not stoppage of the heart; heart failure occurs when the heart is not working efficiently as a pump. (2) Heart failure may carry a grave prognosis. (3) Appropriate therapy includes medical therapy, cardiac catheterization, and possible surgery. (4) Generally, the younger the patient, the more unfavorable the prognosis will be. (5) If the lesion is treatable, most patients do not require medications for life. (6) Congenital heart disease usually does not confine the patient to a wheel chair. Most patients with congenital heart disease have a normal exercise tolerance.

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Chest Pain in Children: Identifying a Source

JOEL I. BRENNER MD, RICHARD E. RINGEL MD, and MICHAEL A. BERMAN MD

Dramatic media attention to the sudden unexpected deaths of celebrities and trained athletes engaged in sports activities focuses a teenager's attention on chest pain as a possible sign of cardiac disease. Educational efforts of organizations such as the American Heart Association improve public awareness of cardiac well-being but also may raise concern about perceived illness where none exists.

From the Department of Pediatrics, Division of Pediatric Cardiology, University of Maryland School of Medicine, 655 W. Baltimore St., Baltimore, MD 21201.

Chest pain in children and adolescents is a growing concern. The issue prompted discussion at the American Academy of Pediatrics meeting, "Update in Pediatric Cardiology" in November 1984[1] and at the American College of Cardiology annual meeting in March 1985.[2] Chest pain has attracted even the attention of cartoonist Charles Schulz, who portrayed Sally (Charlie Brown's younger sister) complaining of the stress of school. Her awareness of her coronaries constricting prevented her from doing homework. On a professional level, two recent review articles in *Pediatric Clinics of North America* addressed the problem.[3,4]

Renewed emphasis on evaluation of pediatric patients with chest pain relates to both medical and social issues. The emphasis on sports and physical fitness at increasingly younger ages places both physical and psychological stress on children not yet able to cope. These factors, coupled with the medical community's awareness of rare and potentially fatal cardiac anomalies that may precipitate chest pain, increase concern over proper evaluation of a child with this complaint. Chest pain has become a major cause of referral to Pediatric Cardiology at the University of Maryland Hospital.

In attempting to thoroughly evaluate the child with chest pain, the referring physician actually may augment concern about a symptom that is unlikely to be of cardiac origin. In addition, he or she may initiate a prolonged and expensive diagnostic evaluation.

This article provides a framework emphasizing diagnostic and therapeutic issues of cardiac disease that may result in chest pain in children. The discussion will include nontraumatic thoracic, gastrointestinal, and psychogenic disturbances that are likely to produce symptoms of chest pain and prompt evaluation. For the pediatric cardiologist, identifying structural or functional cardiac disease remains the main issue. Assuring children and parents of the patients' cardiac integrity may be a vitally important role, and the primary care provider can perform this task for most children, referring those few who, based on careful history and physical exam, warrant further investigation.

Structural Cardiovascular Abnormalities

Concern about structural cardiac disease most often occurs when symptoms of chest pain are associated with physical findings of a heart murmur. Structural abnormalities of the heart severe enough to produce ischemic chest pain, to result in altered cardiac output, and to lead to syncope or even sudden death are a small group of problems that can be identified by careful physical examination and appropriate laboratory studies. However, Lambert's cooperative study of sudden death from cardiac disease in children included eight patients with previously undiagnosed heart lesions.[5] Chest pain was not a prodrome of their demise. In a postmortem study of 29 young athletes with sudden unexpected death, Maron noted that only 7 subjects had suspected cardiac disease prior to their death and only 2 had symptoms of chest pain.

Left ventricular (LV) outflow tract obstruction, whether hypertrophic obstructive cardiomyopathy, aortic valve stenosis, or discrete subvalve aortic stenosis, represents the most frequently encountered group of lesions that produce a recognized risk of ischemic myocardial dysfunction in children.[6,7] When obstruction is severe, the resultant hypertrophy of the left ventricle impairs diastolic coronary perfusion of the subendocardial region. This sequence of events produces the substrate for ischemia and the potential for lethal ventricular rhythm disturbance.

Physical findings should permit determination of the presence of LV outflow tract obstruction; echocardiographic (ECG) examination can localize the level of obstruction and determine its severity. Fixed LV outflow tract obstruction, whether valve or subvalve, should produce a harsh systolic ejection murmur heard well at the upper right sternal border with carotid radiation, often associated with a thrill. Additional findings of an aortic insufficiency murmur may suggest subvalve membranous obstruction. Hypertrophic obstructive left ventricular disease (hypertrophic obstructive cardiomyopathy [HOCM], idiopathic hypertrophic subaortic stenosis [IHSS]) may vary considerably depending on the degree of left ventricular filling. In addition to variable outflow tract murmur, concentric or eccentric hypertrophy of the left ventricle may result in diminished compliance and produce a loud apical filling sound (S4). While it may be difficult to differentiate mild aortic valve narrowing from a benign aortic "flow murmur," mild aortic stenosis should not be a consideration in ischemic chest pain. Concern about hypertrophic myopathy should prompt a careful review

of family history for evidence of recurrent syncope or premature cardiac death, given the autosomal dominant pattern of inheritance.

In all these lesions, specific diagnosis rests on two-dimensional echocardiographic-doppler evaluation. Electrocardiography and routine chest x-ray may be helpful, but neither is sensitive nor specific for these problems. Exercise electrocardiography may aid in the functional assessment of a child with LV outflow tract obstruction and may contribute to the determination of severity of disease,[8] but the sensitivity and specificity of this study have recently come into question.[9] If severe obstruction is suggested by noninvasive evaluation, diagnostic cardiac catheterization and subsequent surgical repair are warranted.

There has been a growing awareness of the prevalence of mitral valve prolapse in the pediatric population and its potential association with chest pain as a presenting symptom. This association is of concern because of the prevalence of mitral valve prolapse, which ranges from 5 to 22 percent in a young female population.[10,11] Chest pain is a well described but uncommon feature of the syndrome, first described in 1963 by Barlow.[12] Bissett reported 119 children with mitral valve prolapse; 21 presented with nonexertional vague chest pain as their chief complaint.[13] Pain is presumed to result from papillary muscle and/or left ventricular endocardial ischemia. Should the pain be associated with an additional complaint of palpitations, rhythm disturbance needs to be considered.

Cardiac examination with the patient supine, sitting, and standing is mandatory to elicit the findings of a mid-systolic click and late systolic murmur of mitral insufficiency; one or both may be present but may vary considerably with position as well as from examination to examination. Specific diagnostic studies (two-dimensional and M-mode echocardiography) also may exclude associated cardiac defects. Care must be taken in this evaluation to prevent false positive studies, especially on M-mode echo examination alone. The accurate diagnosis of mitral valve prolapse depends on transducer angulation and accurate visualization of the free edge of leaflets of the mitral valve where anterior and posterior leaflets coapt in early systole.[14]

Given the variability of physical findings, great care should be exercised in making this diagnosis and, most important, in explaining mitral valve prolapse to the older child and his/her parents. Acceptance and understanding of the diagnosis may be determined by the initial presentation made by the pediatrician or family practitioner. Rarely are limitations on exercise mandated by the presence of mitral valve prolapse.

The association of dysrhythmia and mitral valve prolapse in pediatric patients is well documented, but clinical implications of these findings are less clear. Pickoff noted several children initially presenting with premature ventricular contractions (PVCs) who later developed evidence of mitral valve prolapse on examination or echocardiography.[15] Kavey reported 103 consecutive patients with mitral valve prolapse; all were referred for evaluation of a murmur or a click.[16] Sixteen (15.5 percent) had chest pain. Twenty-eight percent of the control population referred for evaluation of symptoms potentially cardiac in origin complained of chest pain. Serious ventricular rhythm disturbance was noted in 18.5 percent of the prolapse patient population during treadmill exercise and 24-hour ambulatory ECG monitoring. Disturbingly, neither physical examination, ECG, nor symptoms correlated with PVCs.

Seen from another perspective, Chesler reviewed the findings associated with sudden death in mitral valve prolapse in a predominately young adult population.[17] Of fourteen subjects, only two were noted to have chest pain associated with palpitations and ventricular ectopy as well as findings of mitral insufficiency. While commenting about the underlying pathologic findings of endocardial friction lesions and coronary emboli from fibrin deposition in the mitral valve-left atrial junction, Chesler acknowledges that the risk of sudden death in patients with isolated mid-systolic click is quite small.

In Pantell's study of 100 children with chest pain seen in a primary care setting, only one patient was determined to have mitral valve prolapse believed to relate to the presenting complaint. Therefore, despite recent concern about the association of mitral valve prolapse in chest pain, for the child with a negative family history and isolated mid-systolic click, chest pain should be an unusual complaint.[18]

A distinctly unusual malformation of the coronary arteries has received undue attention from the American Academy of Pediatrics in its recent guidelines for sports medicine, *Health Care For Young Athletes.*[19] The publication refers to the risk of sudden death resulting from a normal left coronary artery arising in an anomalous fashion from the anterior sinus of Valsalva and coursing between the aorta and main pulmonary artery to reach its usual distribution. During periods of exercise and high cardiac output, this anomalous coronary artery may be compressed, resulting in ventricular ischemia. Congenital anomalies of the coronary arteries have long been recognized as a cause of anginal chest pain in infants, children, and adolescents.[20]

The best known abnormality remains anomalous origin of the left coronary artery from the main pulmonary artery, which may present in infancy as a catastrophic picture associated with myocardial infarction but also may be present in older children and adults if adequate collateral vessels have formed and left ven-

tricular myocardial perfusion is not suddenly compromised.[21] Other anomalies of the coronary arteries, such as coronary arterial fistula, coronary ostial stenosis, or atresia and anomalous origin of the right coronary artery, have the potential to produce ischemic left ventricular pain and result in myocardial infarction and sudden death.

Historical evidence of exercise-induced anginal chest pain, especially when associated with syncope and/or documented rhythm disturbance, should lead to an extensive cardiac evaluation. Electrocardiography (including exercise testing and ambulatory holter monitoring), echocardiography to evaluate ventricular wall motion abnormalities, and angiography to define coronary arterial distribution should be considered in an effort to explain patient symptoms. A careful history remains the mainstay in suspecting this type of abnormality. Physical examination may be normal or may manifest evidence of ventricular dysfunction (a gallop rhythm) or a pansystolic murmur of mitral insufficiency. An aggressive evaluation must proceed to prevent progressive disability and avoid risk of sudden death.

The significance of chest pain in children with known cardiac disease deserves brief mention. Hemodynamically mild lesions, whether due to obstructive lesions of the right or left ventricles or to an intracardiac shunt, should not produce myocardial ischemia. These abnormalities, if properly diagnosed and appropriately explained to both child and parent, should not predispose to medical or psychological morbidity. Longitudinal follow-up by a pediatric cardiologist or primary care provider should reinforce the benign nature of the defect and provide continued reassurance for the family.

The issue of recurrent chest pain in children with severe operated or unoperated congenital heart disease as a portent of sudden death was reviewed in studies by Lambert and Thornback.[22,23] Children with severe aortic valve stenosis or IHSS, primary or secondary pulmonary vascular obstructive disease, or cyanotic heart disease (including severe right ventricular (RV) outflow tract obstruction) constitute groups at risk for ischemic or arrhythmogenic sudden death. However, death occurred in 58 percent of children while they were inactive; anginal chest pain was not reported as a prodrome in any patient dying suddenly. Thus, the risk of cardiac disability, syncope, or sudden death can be minimized only by early detection and aggressive surgical management of severe structural heart disease.

Acquired Coronary Arterial and Myocardial Disease

Inflammatory coronary artery abnormalities received little attention in pediatric literature until the explosion of information dealing with Kawasaki's disease. Coronary aneurysms, now well described by angiographic and echocardiographic imaging, occur in 15 percent of children with Kawasaki's disease.[24] While half the coronary lesions are said to regress, the long-term outlook remains uncertain.[25] A fatal outcome has been noted in 1 to 2 percent of affected children during the first few months of illness, generally from myocardial infarction or dysrhythmia.

Present recommendations for evaluation of infants and children with Kawasaki's disease are divided into several stages. During the acute phase of the illness (heralded by palmar erythema and induration, bulbar conjunctivitis, erythema of the oral mucosa, and prolonged, unremitting fever), cardiac evaluation should be designed to detect rhythm disturbance, pericardial effusion, and myocarditis. An electrocardiogram and two-dimensional echocardiogram should be performed in the first one to two weeks of illness for this purpose. Follow-up studies at one and three months following the onset of acute illness should be undertaken to identify children with subsequent aneurysm formation in the coronary arterial system. Approximately 90 percent of children with coronary artery aneurysms should be identified by this plan, and they can be followed every six to twelve months on long-term, low-dose aspirin therapy. When proximal coronary lesions are identified by 2-D echo and are noted to resolve, aortography or coronary artery angiography may be indicated to determine whether distal lesions persist and if the proximal aneurysms have thrombosed or recanalized.

Kegel's report of a twelve-year-old boy dying suddenly from an extensive myocardial infarction four years after an episode of Kawasaki's disease emphasizes the need for continued evaluation of these children.[26] Follow-up of children affected by recent epidemics in the United States and the 1982 epidemic in the state of Maryland will help define the natural history of this syndrome.

Inflammatory pericardial disease may result from viral, bacterial, rheumatic, or autoimmune processes. Coxsackie virus, hemophilus influenza, and staphylococcus aureus are commonly implicated infectious agents in acute pericarditis in childhood. Okoroma noted four of twenty-five children (16 percent) complaining of chest pain as a presenting sign of acute bacterial pericarditis.[27] Pericardial effusion occurring following blunt chest trauma also must be considered in the adolescent presenting with chest pain. Occasion-

ally, symptoms of respiratory distress due to cardiac tamponade from a large pericardial effusion may result. This autoimmune reaction more commonly is seen in patients following cardiothoracic surgery.[28] Acute onset of dull precordial pain may be noted in spontaneous pneumopericardium. Contiguous pulmonary infection or tumor process may result in pericardial irritation and pain that generally varies with respiration and position. Chest x-ray, electrocardiogram, and echo may be required to make a specific diagnosis in these entities.

Chronic, "burned-out" myocarditis, or acute inflammatory myocarditis may present with chest pain resulting either from inflammation, ischemia, or arrhythmia. In the setting of an acute febrile illness, chest x-ray and echocardiography may pinpoint the diagnosis of myocardial dysfunction. Despite a high index of suspicion, pathologic findings of myocarditis often are noted in teenagers and young adults with sudden unexpected death without a clear prodrome of ischemic chest pain and progressive dyspnea. This catastrophic presentation of myocardial disease may not be totally preventable.[29]

Rhythm Abnormality

Chest pain may be associated with a variety of rhythm abnormalities, likely based on physiologic alterations of cardiac output with a resulting increased subendocardial wall stress and diminished diastolic coronary perfusion. This sequence of events can be noted in any sustained tachyarrhythmia and generally will require several hours of abnormal rhythm to produce evidence of ventricular dysfunction. This pathophysiologic abnormality must be differentiated from the subjective sensation of chest discomfort associated with palpitations or forceful heart beat that may reflect awareness of an underlying rhythm abnormality but also may reflect musculoskeletal or chest wall abnormality.

The paroxysmal nature of the more common supraventricular tachycardia and the uncommon ventricular tachycardia may cause atypical chest pain not consistently associated with exercise. When chest discomfort is associated with palpitations or dizziness, and certainly when it is associated with syncope, a resting ECG, 24-hour ambulatory ECG monitoring, and intracardiac electrophysiologic studies may be required. Scalar electrocardiography may provide evidence for frequent premature atrial beats, demonstrate a short PR interval with associated wide QRS (the classic features of ventricular pre-exitation Wolff-Parkinson-White Syndrome), findings suggesting a suspected rhythm abnormality.

For the patient with chest pain not associated with syncope, a reasonable effort should be made to correlate patient symptoms with electrocardiographic findings on ambulatory monitoring or by use of an event recorder with telephonic transmission of ECG findings to a central receiving station. If patient symptoms occur without Holter confirmation, reassurance and explanation, rather than anti-arrhythmic medication, may be all that is required from the cardiologist.

Occasionally, patients will not have their usual symptoms despite three successive days of Holter monitoring, and the decision to treat will be based on other findings. If supraventricular tachycardia is demonstrated, many children and adolescents can be instructed to terminate their arrhythmia via Valsalva maneuver, carotid massage, facial or upper arm emersion in ice water, or by drinking ice water. Occasionally, maintenance drug therapy is required to control episodes of prolonged supraventricular tachycardia or to minimize the patient's symptoms. Prior to establishing either form of therapy, however, the patient and his/her parents deserve detailed explanation of the nature and generally benign prognosis of paroxysmal supraventricular tachycardia in otherwise healthy children.[30] The same reassurance can be provided to patients with isolated premature ventricular contractions and to those with brief episodes of nonsustained ventricular tachycardia.[31] Jacobson noted a 2.8 percent incidence of isolated PVCs in healthy children.[32] The presence of ventricular ectopy with associated symptoms of chest pain and palpitations is unusual, and Holter confirmation may provide reassurance of the benign nature of the problem. Suppressive medical therapy generally is not indicated.

Noncardiac Chest Pain

Having presented a brief overview of the major categories of cardiac concerns that need to be addressed in the child and adolescent presenting with chest pain, it is important to stress that only rarely are cardiac abnormalities found in children presenting with this complaint. A detailed medical history (including duration of symptoms, inciting events, the nature of the pain, and associated symptoms) when coupled with a careful cardiac examination will allow exclusion of most of the aforementioned cardiac disorders. Three recent studies addressing the issue of chest pain in adolescents and children, with a combined patient population of 242 adolescents, identified only one subject with abnormal cardiac findings: evidence of mitral valve prolapse on examination and echocardiography. Appreciation of the noncardiac issues are of paramount interest, as stressed by the studies of Driscoll,[33] Brown[34] and

Pantell[35] and reviews by Coleman[36] and Perry.[37]

In a patient population derived from the adolescent clinic at the University of Alabama, Brown reports 5 percent of patient visits are due to chest or upper abdominal pain, with 79 percent of this group having physical findings of costochondritis responsible for the presenting symptoms. While Brown emphasizes that costochondritis is a benign condition, treated by reassurance and occasionally by analgesics, his findings are not supported by Driscoll and Pantell. In two separate studies with similar patient populations, 22 percent and 29 percent of teenagers presenting with chest pain were believed to have musculoskeletal abnormalities or costochondritis. They note that in patients with musculoskeletal pain, a chest x-ray occasionally will be helpful to identify narrowing of the thoracic vertebral disc space causing radicular pain or to identify a rib cage abnormality, but in most situations the diagnosis of musculoskeletal chest pain is based on the physical findings of tenderness along a costochondral junction or reproducibility of pain by motion.

Breast-related problems were noted in five of Pantell's 100 adolescents; four of these five patients were boys. Concern about gynecomastia in pubertal males or fear of breast cancer in either sex may produce considerable psychological trauma that may be expressed by complaints of chest pain.

The occurrence of chest pain in conjunction with pulmonary disease in this ambulatory adolescent setting was relatively small, accounting for less than 10 percent of the combined patient population. Prospective study of the use of chest x-ray in evaluating patients with acute chest complaints noted a low yield of positive x-rays in patients less than 40 years old with normal chest exam and no history of cough or hemoptysis.[38] In a teenage or young adult population, chronic marijuana use also may result in chest pain, with little likelihood of abnormal findings on chest x-ray. Lantner stresses careful history taking or use of urine screening for cannabinoids in explaining the underlying etiology of chronic chest pain secondary to marijuana use.[39]

Gastrointestinal disorders were a rare problem in the combined series. This is in contradistinction to findings in an adult population, where esophageal and gastrointestinal disturbances accounted for chest pain in nearly 25 percent of adult patients.[40] Detailed dietary history should be reviewed and relationship of pain to meals investigated. A trial of antacid therapy or avoidance of milk products in individuals with suspected lactose intolerance should be considered.

Hyperventilation was a component of chest pain in nearly all of Pantell's patients and was thought to be a primary concern in 20 percent of his group. The chest discomfort is presumed to occur from hypocapneic alkalosis with resulting coronary vasoconstriction, aerophagia resulting in stomach distention, spasm of the left hemidiaphragm, or transient rhythm disturbance. Hyperventilation often was associated with paresthesia and light-headedness. The nature of underlying events responsible for the hyperventilation could not be established.

In nearly half of Driscoll's and Pantell's combined population, no specific organic diagnosis was made. In an effort to further investigate the significance of idiopathic chest pain, Asnes evaluated 123 patients presenting to an urban pediatric cardiac clinic with this complaint.[41] In 36 of these patients, no organic etiology could be found but a clear emotional origin for the pain was demonstrated. A specific school or family stress, death or separation, disability or physical illness was causally related to the onset of chest pain. The stress or loss can be either real or imagined. Asnes also noted a positive family history of chest pain and recurrent somatic complaints in approximately half this population.

Friedman has addressed the concept of chest pain as a conversion symptom, noting this type of symptom transformation is more common in adolescents than in children.[42,43] He stresses that conversion symptoms in adolescents are more likely to be alarming and consist of chest pain or fainting spells, while children more frequently will complain of recurrent abdominal pain, headaches, or dizziness. Conversion symptoms may appear as early as age seven or eight years and are more likely to occur in females.

Diagnosis of conversion symptoms requires strict adherence to established criteria, including symbolic meaning of the symptoms, apparent lack of concern about symptoms, a role model for the symptoms, and distinctive description. Patients frequently will display patterns of behavior that may be described as hysterical. The patient will use the symptoms to reduce anxiety in an effort to cope with environmental stress. The history and physical findings in this group of patients usually are inconsistent with anatomic and physiologic concepts.

Recognition of the scope of the underlying psychogenic issues may best be detected by the primary care physician during his/her ongoing involvement with the child and family. Follow-up visits dealing with specific somatic complaints of chest pain may be indicated. Symptoms that are idiopathic or potentially psychogenic in origin are more likely to persist and induce compliance with follow-up visits as noted by Driscoll. Referral for behavioral evaluation and psychological or psychiatric counseling is an option available to the

pediatrician or family practitioner depending on his/her level of expertise and familiarity in managing these psychogenic disorders.[44]

The association of chest pain with depression recently has been commented on by Kashani.[45] Drawing on a pediatric cardiology outpatient population, 13 of 100 children, age 16 to 18, met criteria for a major depressive disorder (as outlined in the *Diagnostic and Statistical Manual of Mental Disorders*).[46] All four children referred for evaluation of chest pain were found to be in this depressive disorder group, raising the possibility that chest pain could be an accompanying symptom of depression in children. Pantell also noted seven children in his group of 100 who had depression but described this as an associated medical condition that was not causative. The implication for accurate diagnosis extends beyond the thoroughness of medical history and physical examination into psychosocial issues that may prompt a child's somatic complaints.

Summary

Chest pain in children is an increasing concern that raises anxiety both in the patient, his/her family, and the primary care physician. Children with chest pain are apprehensive and uncertain; many believe they are having a heart attack. Frustration may be created for the primary care physician; the diagnostic process may not allow definition of a specific organic abnormality. Overdependence on routine cardiac screening tests (ECG, chest x-ray, echocardiogram) in this low-risk age group is not likely to provide the desired result for either the physician or the patient. Noninvasive cardiac evaluation rarely is more useful in discriminating between the presence or absence of cardiac disease than is a careful physical examination by a qualified examiner.[47] For the less confident physician, equating negative test results with the absence of heart disease or, conversely, equating positive test results with the presence of heart disease will lead to a high proportion of erroneous diagnoses. Noninvasive tests are helpful only when appropriately applied. In an adolescent population at relatively low risk for cardiac disease, this admonition remains a central theme.

Subspecialty referral may be appropriate when specific concerns have been defined. Pediatric cardiologists should be able to resolve the issue of the presence or absence of heart disease. If structural cardiac disease becomes a concern, the severity of the problem usually can be assessed noninvasively. Anginal symptoms or exercise-induced syncope always should initiate a detailed and aggressive evaluation. When concern about cardiac disease is not substantiated by the primary care physician, and no specific organic etiology is determined, then longitudinal follow-up, psychosocial surveillance, and appropriate reassurance for the child and his/her family are the therapeutic issues of the day.

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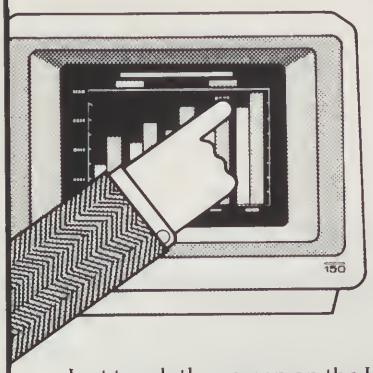
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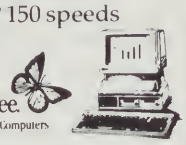
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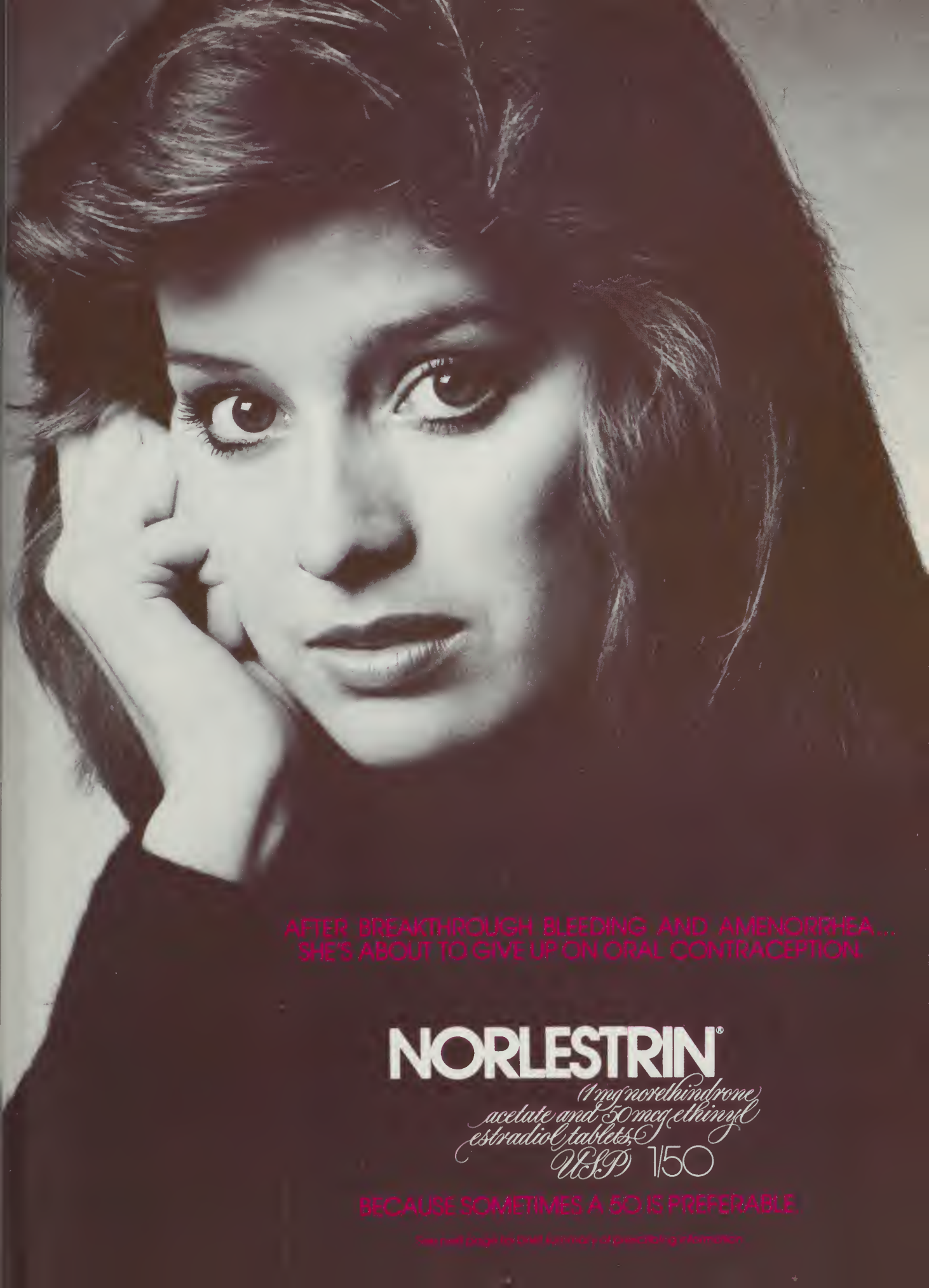
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BECAUSE SOMETIMES A 50 IS PREFERABLE.
See next page for brief summary of prescribing information.

Brief Summary of Prescribing Information
NORLESTRIN® (norethindrone acetate and ethinyl estradiol tablets, USP)

See section under **Special Notes on Administration and HOW SUPPLIED.**
Before prescribing, please see full prescribing information. A Brief Summary follows.

DESCRIPTION
Norlestrin Products are progestogen-estrogen combinations.

INDICATIONS AND USAGE
Norlestrin Products are indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

In clinical trials with Norlestrin 1/50 involving 25,983 therapy cycles, there was a pregnancy rate of 0.05 per 100 woman-years; in clinical trials with Norlestrin 2.5/50 involving 96,388 cycles, there was a pregnancy rate of 0.22 per 100 woman-years.

Dose-Related Risk of Thromboembolism from Oral Contraceptives: Studies have shown a positive association between the dose of estrogens in oral contraceptives and the risk of thromboembolism. It is prudent and in keeping with good principles of therapeutics to minimize exposure to estrogen. The oral contraceptive prescribed for any given patient should be that product which contains the least amount of estrogen that is compatible with an acceptable pregnancy rate and patient acceptance.

CONTRAINDICATIONS
1. Thrombophlebitis or thromboembolic disorders
2. A past history of deep-vein thrombophlebitis or thromboembolic disorders
3. Cerebral vascular or coronary artery disease
4. Known or suspected carcinoma of the breast
5. Known or suspected estrogen-dependent neoplasia
6. Undiagnosed abnormal genital bleeding
7. Known or suspected pregnancy (See WARNING No. 5)
8. Benign or malignant liver tumor which developed during the use of oral contraceptives or other estrogen-containing products.

WARNINGS

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

The use of oral contraceptives is associated with increased risk of several serious conditions including thromboembolism, stroke, myocardial infarction, hepatic adenoma, gallbladder disease, and hypertension. Practitioners prescribing oral contraceptives should be familiar with the following information relating to these risks.

1. *Thromboembolic Disorders and Other Vascular Problems.* An increased risk of thromboembolic and thrombotic disease associated with the use of oral contraceptives is well-established. Studies have demonstrated an increased risk of fatal and nonfatal venous thromboembolism and stroke, both hemorrhagic and thrombotic.

Cerebrovascular Disorders: In a collaborative study in women with and without predisposing causes, it was estimated that the risk of hemorrhagic stroke was 2.0 times greater in users than nonusers, and the risk of thrombotic stroke was 4.0 to 9.5 times greater.

Myocardial Infarction: An increased risk of myocardial infarction associated with oral contraceptives has been reported confirming a previously suspected association. These studies found that the greater the number of underlying risk factors (cigarette smoking, hypertension, hypercholesterolemia, obesity, diabetes, history of preeclamptic toxemia) for coronary artery disease, the higher the risk of developing myocardial infarction, regardless of whether the patient was an oral contraceptive user or not. Oral contraceptives, however, were found to be a clear additional risk factor.

It has been estimated that users who do not smoke (smoking is considered a major predisposing condition to myocardial infarction) are about twice as likely to have a fatal myocardial infarction as nonusers who do not smoke. Oral contraceptive users who are smokers have about a fivefold increased risk of fatal infarction compared to users who do not smoke, but about a tenfold to twelvefold increased risk compared to nonusers who do not smoke. The amount of smoking is also an important factor.

Risk of Dose: In an analysis of data, British investigators concluded that the risk of thromboembolism, including coronary thrombosis, is directly related to the dose of estrogen used in oral contraceptives; however, the quantity of estrogen may not be the sole factor involved.

Persistence of Risk: Two studies have suggested that an increased risk may persist for as long as 6 years after discontinuation of oral contraceptive use for cerebrovascular disease and 9 years for myocardial infarction. In addition, a prospective study suggested the persistence of risk for subarachnoid hemorrhage.

Estimate of Excess Mortality from Circulatory Diseases: The risk of diseases of the circulatory system is concentrated in older women, in those with a long duration of use, and in cigarette smokers.

A study of available data from a variety of sources concluded that the mortality associated with all methods of birth control is low and below that associated with childbirth, with the exception of oral contraceptives in women over 40 who smoke.

The risk of thromboembolic and thrombotic diseases associated with oral contraceptives increases with age alter approximately age 30 and, for myocardial infarction, is further increased by hypertension, hypercholesterolemia, obesity, diabetes, or history of preeclamptic toxemia, and especially by cigarette smoking.

The physician and the patient should be alert to the earliest manifestations of thromboembolic and thrombotic disorders. Should any occur or be suspected, the drug should be discontinued immediately.

A fourfold to sixfold increased risk of postsurgery thromboembolic complications has been reported in users. If feasible, oral contraceptives should be discontinued at least four weeks before surgery of a type associated with an increased risk of thromboembolism or prolonged immobilization.

2. *Ocular Lesions.* Neuro-ocular lesions, such as optic neuritis or retinal thrombosis, have been associated with the use of oral contraceptives. Discontinue the oral contraceptive if there is unexplained sudden or gradual, partial, or complete loss of vision; onset of proptosis or diplopia; papilledema; or retinal vascular lesions.

3. *Carcinoma.* Long-term continuous administration of estrogen in certain animal species increases the frequency of carcinoma of the breast, cervix, vagina, and liver.

In humans, an increased risk of endometrial carcinoma associated with the prolonged use of exogenous estrogen in postmenopausal women has been reported. However, there is no evidence suggesting increased risk of endometrial cancer in users of conventional combination or progestogen-only oral contraceptives.

Studies found no evidence of increase in breast cancer in women taking oral contraceptives; however, an excess risk in users with documented benign breast disease was reported.

There is no confirmed evidence of an increased risk of cancer associated with oral contraceptives. Close clinical surveillance of users is, nevertheless, essential. In cases of undiagnosed persistent or recurrent abnormal vaginal bleeding, appropriate diagnostic measures should be taken to rule out malignancy. Women with a strong family history of breast cancer, or who have breast nodules, fibrocystic disease, or abnormal mammograms, should be monitored with particular care.

4. *Hepatic Tumors.* Benign hepatic adenomas have been found to be associated with oral contraceptives. Because hepatic adenomas may rupture and may cause death through intra-abdominal hemorrhage, they should be considered in women presenting abdominal pain and tenderness, abdominal mass, or shock.

A few cases of hepatocellular carcinoma have been reported in women taking oral contraceptives. The relationship of these drugs to this type of malignancy is not known at this time.

5. *Usage in or Immediately Preceding Pregnancy; Birth Defects in Offspring, and Malignancy in Female Offspring.* During early pregnancy, female sex hormones may seriously damage the offspring.

An increased risk of congenital anomalies, including heart defects and limb defects, has been reported with the use of oral contraceptives in pregnancy.

There is some evidence that triploidy and possible other types of polyploidy are increased among abortuses from women who become pregnant soon after ceasing oral contraceptives.

Pregnancy should be ruled out before continuing an oral contraceptive in any patient who has missed two consecutive menstrual periods. If the patient has not adhered to the schedule, the possibility of pregnancy should be considered at the time of the first missed period, and oral contraceptives should be withheld until pregnancy has been ruled out. If pregnancy is confirmed, the patient should be apprised of the potential risks to the fetus and the advisability of continuation of the pregnancy should be discussed.

Women who discontinue oral contraceptives with the intent of becoming pregnant should use an alternate form of contraception for a period of time before attempting to conceive.

Administration of progestogen-only or progestogen-estrogen combinations to induce withdrawal bleeding should not be used as a test of pregnancy.

6. *Gallbladder Disease.* Studies report an increased risk of surgically confirmed gallbladder disease in users of oral contraceptives.

7. *Carbohydrate and Lipid Metabolic Effects.* Because decreased glucose tolerance has been observed in a significant percentage of patients, prediabetic and diabetic patients should be carefully observed while receiving oral contraceptives.

An increase in triglycerides and total phospholipids has been observed.

8. *Elevated Blood Pressure.* An increase in blood pressure has been reported in patients receiving oral contraceptives. The prevalence in users increases with longer exposure. Age is also strongly correlated with development of hypertension. Women who previously have had hypertension during pregnancy may be more likely to develop elevation of blood pressure.

9. *Headache.* Onset or exacerbation of migraine or development of headache of a new pattern which is recurrent, persistent, or severe, requires discontinuation of oral contraceptives.

10. *Bleeding Irregularities.* Breakthrough bleeding, spotting, and amenorrhea are frequent reasons for patients discontinuing oral contraceptives. In breakthrough bleeding, nonfunctional causes should be borne in mind. In undiagnosed abnormal bleeding from the vagina, adequate diagnostic measures are indicated to rule out pregnancy or malignancy.

Women with a past history of oligomenorrhea or secondary amenorrhea, or young women without regular cycles should be advised that they may have a tendency to remain anovulatory or to become amenorrheic after discontinuation of oral contraceptives.

11. *Ectopic Pregnancy.* Ectopic as well as intrauterine pregnancy may occur in contraceptive failures.

12. *Breast-Feeding.* Oral contraceptives may interfere with lactation. Furthermore, a small fraction of the hormonal agents in oral contraceptives has been identified in the milk of mothers receiving these drugs.

PRECAUTIONS
1. A complete medical and family history should be taken prior to the initiation of oral contraceptives. The pretreatment and periodic physical examinations should include special reference to blood pressure, breasts, abdomen, and pelvic organs, including Papanicolaou smear and relevant laboratory tests. As a general rule, oral contraceptives should not be prescribed for longer than one year without another examination.

2. Preexisting uterine leiomyomata may increase in size.

3. Patients with a history of psychic depression should be carefully observed and the drug discontinued if depression recurs to a serious degree.

4. Oral contraceptives may cause fluid retention and should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated.

5. Patients with a past history of jaundice during pregnancy have an increased risk of recurrence of jaundice. If jaundice develops, the medication should be discontinued.

6. Steroid hormones may be poorly metabolized and should be administered with caution in patients with impaired liver function.

7. Users may have disturbances in normal tryptophan metabolism, which may result in a relative pyridoxine deficiency.

8. Serum folate levels may be depressed.

9. The pathologist should be advised of oral contraceptive therapy when relevant specimens are submitted.

10. Certain endocrine and liver function tests and blood components may be affected: (a) Increased sulfobromophthalein retention. (b) Increased prothrombin and factors VII, VIII, IX, and X; decreased antithrombin 3; increased norepinephrine-induced platelet aggregability. (c) Increased thyroid-binding globulin (TBG) leading to increased circulating total thyroid hormone. (d) Decreased pregnanediol excretion. (e) Reduced response to metyrapone test.

Drug Interactions: Reduced efficacy and increased incidence of breakthrough bleeding have been associated with concomitant use of rifampin. A similar association has been suggested with barbiturates, phenylbutazone, phenytoin sodium, tetracycline, and ampicillin.

ADVERSE REACTIONS
An increased risk of the following serious adverse reactions has been associated with oral contraceptives: thrombophlebitis; pulmonary embolism; coronary thrombosis; cerebral thrombosis; cerebral hemorrhage; hypertension; gallbladder disease; benign hepatomas; congenital anomalies.

There is evidence of an association between the following conditions and the use of oral contraceptives although additional confirmatory studies are needed: mesenteric thrombosis; neuro-ocular lesions, eg, retinal thrombosis and optic neuritis.

The following adverse reactions have been reported in patients receiving oral contraceptives and are believed to be drug related: nausea and/or vomiting, usually the most common adverse reactions, occur in approximately 10% or less of patients during the first cycle. Other reactions, as a general rule, are seen much less frequently or only occasionally: gastrointestinal symptoms; breakthrough bleeding; spotting; change in menstrual flow; dysmenorrhea; amenorrhea during and after treatment; temporary infertility after discontinuance of treatment; edema; chloasma or melasma; breast changes; change in weight; change in cervical erosion and cervical secretion; possible diminution in lactation when given immediately postpartum; cholestatic jaundice; migraine; increase in size of uterine leiomyomata; rash (allergic); mental depression; reduced tolerance to carbohydrates; vaginal candidiasis; change in corneal curvature; intolerance to contact lenses.

The following adverse reactions have been reported and the association has been neither confirmed nor refuted: premenstrual-like syndrome; cataracts; changes in libido; chorea; changes in appetite; cystitis-like syndrome; headache; nervousness; dizziness; hirsutism; loss of scalp hair; erythema multiforme; erythema nodosum; hemorrhagic eruption; vaginitis; porphyria.

Special Notes on Administration
Menstruation usually begins two or three days, but may begin as late as the fourth or fifth day, after discontinuing medication.

After several months on treatment, bleeding may be reduced to a point of virtual absence; reduced flow may be a result of medication and not indicative of pregnancy.

HOW SUPPLIED
Norlestrin [21] 1/50 is available in compacts each containing 21 tablets. Each tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

Norlestrin [21] 2.5/50 is available in compacts each containing 21 tablets. Each tablet contains 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

Norlestrin [Fe] 1/50 is available in compacts each containing 21 yellow tablets and 7 brown tablets. Each yellow tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Each brown tablet contains 75 mg of ferrous fumarate, USP. Available in packages of five compacts and packages of five refills.

Norlestrin [FE] 2.5/50 is available in compacts each containing 21 pink tablets and 7 brown tablets. Each pink tablet contains 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Each brown tablet contains 75 mg of ferrous fumarate, USP. Available in packages of five compacts and packages of five refills.

Norlestrin [28] 1/50 is available in compacts each containing 21 yellow tablets and 7 white inert tablets. Each yellow tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

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References:
1. Strauss WE, McIntyre KM, Parisi AF, et al: Safety and efficacy of diltiazem hydrochloride for the treatment of stable angina pectoris: Report of a cooperative clinical trial. Am J Cardiol 49:560-566, 1982.
2. Pool PE, Seagren SC, Bonanno JA, et al: The treatment of exercise-inducible chronic stable angina with diltiazem: Effect on treadmill exercise. Chest 78 (July suppl):234-238, 1980.

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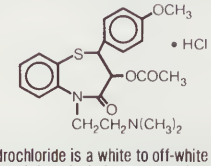
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CARDIZEM® (diltiazem hydrochloride) is a calcium ion influx inhibitor (slow channel blocker or calcium antagonist). Chemically, diltiazem hydrochloride is 1,5-Benzothiazepin-4(5H)one,3-(acetyloxy) -5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-, monohydrochloride,(+) -cis-. The chemical structure is:



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CLINICAL PHARMACOLOGY

The therapeutic benefits achieved with CARDIZEM are believed to be related to its ability to inhibit the influx of calcium ions during membrane depolarization of cardiac and vascular smooth muscle.

Mechanisms of Action. Although precise mechanisms of its antianginal actions are still being delineated, CARDIZEM is believed to act in the following ways:

1. Angina Due to Coronary Artery Spasm: CARDIZEM has been shown to be a potent dilator of coronary arteries both epicardial and subendocardial. Spontaneous and ergonovine-induced coronary artery spasm are inhibited by CARDIZEM.
2. Exertional Angina: CARDIZEM has been shown to produce increases in exercise tolerance, probably due to its ability to reduce myocardial oxygen demand. This is accomplished via reductions in heart rate and systemic blood pressure at submaximal and maximal exercise work loads.

In animal models, diltiazem interferes with the slow inward (depolarizing) current in excitable tissue. It causes excitation-contraction uncoupling in various myocardial tissues without changes in the configuration of the action potential. Diltiazem produces relaxation of coronary vascular smooth muscle and dilation of both large and small coronary arteries at drug levels which cause little or no negative inotropic effect. The resultant increases in coronary blood flow (epicardial and subendocardial) occur in ischemic and nonischemic models and are accompanied by dose-dependent decreases in systemic blood pressure and decreases in peripheral resistance.

Hemodynamic and Electrophysiologic Effects. Like other calcium antagonists, diltiazem decreases sinoatrial and atrioventricular conduction in isolated tissues and has a negative inotropic effect in isolated preparations. In the intact animal, prolongation of the AH interval can be seen at higher doses.

In man, diltiazem prevents spontaneous and ergonovine-provoked coronary artery spasm. It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure and, in exercise tolerance studies in patients with ischemic heart disease, reduces the heart rate-blood pressure product for any given work load. Studies to date, primarily in patients with good ventricular function, have not revealed evidence of a negative inotropic effect; cardiac output, ejection fraction, and left ventricular end diastolic pressure have not been affected. There are as yet few data on the interaction of diltiazem and beta-blockers. Resting heart rate is usually unchanged or slightly reduced by diltiazem.

Intravenous diltiazem in doses of 20 mg prolongs AH conduction time and AV node functional and effective refractory periods approximately 20%. In a study involving single oral doses of 300 mg of CARDIZEM in six normal volunteers, the average maximum PR prolongation was 14% with no instances of greater than first-degree AV block. Diltiazem-associated prolongation of the AH interval is not more pronounced in patients with first-degree heart block. In patients with sick sinus syndrome, diltiazem significantly prolongs sinus cycle length (up to 50% in some cases).

Chronic oral administration of CARDIZEM in doses of up to 240 mg/day has resulted in small increases in PR interval, but has not usually produced abnormal prolongation. There were, however, three instances of second-degree AV block and one instance of third-degree AV block in a group of 959 chronically treated patients.

Pharmacokinetics and Metabolism. Diltiazem is absorbed from the tablet formulation to about 80% of a reference capsule and is subject to an extensive first-pass effect, giving an absolute bioavailability (compared to intravenous dosing) of about 40%. CARDIZEM undergoes extensive hepatic metabolism in which 2% to 4% of the unchanged drug appears in the urine. In vitro binding studies show CARDIZEM is 70% to 80% bound to plasma proteins. Competitive ligand binding studies have also shown CARDIZEM binding is not altered by therapeutic concentrations of digoxin, hydrochlorothiazide, phenylbutazone, propranolol, salicylic acid, or warfarin. Single oral doses of 30 to 120 mg of CARDIZEM result in detectable plasma levels within 30 to 60 minutes and peak plasma levels two to three hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3.5 hours. Desacetyl diltiazem is also present in the plasma at levels of 10% to 20% of the parent drug and is 25% to 50% as potent a coronary vasodilator as diltiazem. Therapeutic blood levels of CARDIZEM appear to be in the range of 50 to 200 ng/ml. There is a departure from dose-linearity when single doses above 60 mg are given; a 120-mg dose gave blood levels three times that of the 60-mg dose. There is no information about the effect of renal or hepatic impairment on excretion or metabolism of diltiazem.

INDICATIONS AND USAGE

1. **Angina Pectoris Due to Coronary Artery Spasm.** CARDIZEM is indicated in the treatment of angina pectoris due to coronary artery spasm. CARDIZEM has been shown effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (resting angina with ST-segment elevation occurring during attacks).
2. **Chronic Stable Angina (Classic Effort-Associated Angina).** CARDIZEM is indicated in the management of chronic stable angina. CARDIZEM has been effective in controlled trials in reducing angina frequency and increasing exercise tolerance.

There are no controlled studies of the effectiveness of the concomitant use of diltiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities.

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

1. **Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
2. **Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
3. **Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
4. **Acute Hepatic Injury.** In rare instances, patients receiving CARDIZEM have exhibited reversible acute hepatic injury as evidenced by moderate to extreme elevations of liver enzymes. (See PRECAUTIONS and ADVERSE REACTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS).

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vitro bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outweigh its potential risks in this situation.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences, as well as their frequency of presentation, are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3% asthenia (1.2%), AV block (1.1%). In addition, the following even were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrence.

Cardiovascular:	Flushing, arrhythmia, hypotension, bradyc dia, palpitations, congestive heart failur syncope.
Nervous System:	Paresthesia, nervousness, somnolenc tremor, insomnia, hallucinations, and amnesi
Gastrointestinal:	Constipation, dyspepsia, diarrhea, vomiting mild elevations of alkaline phosphatase, SGO SGPT, and LDH.
Dermatologic:	Pruritus, petechiae, urticaria, photosensitivity
Other:	Polyuria, nocturia.

The following additional experiences have been noted:

A patient with Prinzmetal's angina experiencing episodes vasospastic angina developed periods of transient asymptomati asystole approximately five hours after receiving a single 60-m dose of CARDIZEM.

The following postmarketing events have been reported infr quently in patients receiving CARDIZEM: erythema multiforme; leu kopenia; and extreme elevations of alkaline phosphatase, SGO SGPT, LDH, and CPK. However, a definitive cause and effect betwee these events and CARDIZEM therapy is yet to be established.

OVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with oral diltiazem has been limited Single oral doses of 300 mg of CARDIZEM have been well tolerate by healthy volunteers. In the event of overdosage or exaggerate response, appropriate supportive measures should be employed i addition to gastric lavage. The following measures may be considered

Bradycardia	Administer atropine (0.60 to 1.0 mg). If ther is no response to vagal blockade, administ isoproterenol cautiously.
High-Degree AV Block	Treat as for bradycardia above. Fixed high degree AV block should be treated with car diac pacing.
Cardiac Failure	Administer inotropic agents (isoproterenol dopamine, or dobutamine) and diuretics.
Hypotension	Vasopressors (eg, dopamine or levarteren bitartrate).

Actual treatment and dosage should depend on the severity of th clinical situation and the judgment and experience of the treatin physician.

The oral/LD_{50}'s in mice and rats range from 415 to 740 mg/k and from 560 to 810 mg/kg, respectively. The intravenous LD_{50}'s i these species were 60 and 38 mg/kg, respectively. The oral LD_{50} i dogs is considered to be in excess of 50 mg/kg, while lethality wa seen in monkeys at 360 mg/kg. The toxic dose in man is not known but blood levels in excess of 800 ng/ml have not been associate with toxicity.

DOSAGE AND ADMINISTRATION

Exertional Angina Pectoris Due to Atherosclerotic Coronary Artery Disease or Angina Pectoris at Rest Due to Coronary Artery Spasm. Dosage must be adjusted to each patient's needs. Starting with 30 mg four times daily, before meals and at bedtime, dosage should be increased gradually (given in divided doses three or four times daily) at one- to two-day intervals until optimum response is obtained. Although individual patients may respond to any dosage level, the average optimum dosage range appears to be 180 to 240 mg/day. There are no available data concerning dosage requirements in patients with impaired renal or hepatic function. If the drug must be used in such patients, titration should be carried out with particular caution.

Concomitant Use With Other Antianginal Agents:

1. **Sublingual NTG** may be taken as required to abort acute anginal attacks during CARDIZEM therapy.
2. **Prophylactic Nitrate Therapy**—CARDIZEM may be safely coadministered with short- and long-acting nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.
3. **Beta-blockers.** (See WARNINGS and PRECAUTIONS.)

HOW SUPPLIED

Cardizem 30-mg tablets are supplied in bottles of 100 (NDC 0088-1771-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1771-49). Each green tablet is engraved with MARION on one side and 1771 engraved on the other. CARDIZEM 60-mg scored tablets are supplied in bottles of 100 (NDC 0088-1772-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1772-49). Each yellow tablet is engraved with MARION on one side and 1772 on the other.

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Noninvasive Assessment of Pediatric Congenital Heart Disease

LOWELL W. PERRY MD

Dr. Perry is Associate Cardiologist, Children's Hospital National Medical Center; Professor of Child Health and Development, George Washington University, Washington, DC.

The diagnosis of congenital heart disease begins with the history and physical examination of the child and is enhanced by special studies. We review the role of x-ray, electrocardiogram, Holter monitoring, and stress testing in the evaluation of congenital heart disease in the pediatric patient.

Chest Roentgenogram

Chest roentgenograms are used to evaluate cardiac dimensions, gross abnormalities in cardiac configuration, cardiac situs, and pulmonary blood flow. We will discuss the role of the posteroanterior (PA) chest film in this respect. To simplify the task, we outline a series of steps to improve your approach to the plain chest film in the pediatric patient.

Step 1 Be certain the PA view is a true PA view. The PA chest film must be taken in full inspiration with the patient as close as possible in a position perpendicular to the x-ray beam. Make certain the supraclavicular notch is directly in front of the spine. A film taken in expiration or with patient rotated can produce false-positive cardiac enlargement or false-positive increased pulmonary flow.

Step 2 Look for associated skeletal defects. Before examining the cardiac silhouette, scan for rib abnormalities that might indicate coarctation of the aorta or old surgery. Evaluate vertebral column. Skeletal defects may be associated with congenital heart defects.

Step 3 Determine the abdominal situs. The stomach bubble should be on the left and the liver on the right. If not, think of asplenia or polysplenia or situs inversus.

Step 4 Establish the side of aortic arch by determining its relationship to the trachea.

Step 5 Evaluate cardiac dimensions and configuration. The cardiothoracic ratio is calculated by dividing the widest dimension of the cardiac silhouette by the widest internal diameter of the chest. The CT ratio is 55 percent or less in normal children. CT ratio is increased when the volume of the heart is increased. When the left ventricle is enlarged the apex of the heart points beneath the diaphragm. When right ventricle is enlarged, the apex of heart points horizontally. Thickening of cardiac muscle generally does not produce significant increases in the CT ratio.

Step 6 Evaluate the pulmonary outflow tract. The pulmonary artery may be dilated, normal, or concave. Pulmonary artery dilatation may indicate pulmonary stenosis, pulmonary vascular obstructive disease, or it may be idiopathic. Extreme dilatation is associated with congenital pulmonary valve insufficiency; this often is associated with emphysema and atelectasis. Concavity of the pulmonary artery segment may indicate pulmonary atresia or extreme pulmonary stenosis as with tetralogy of Fallot.

Step 7 Evaluate the pulmonary vascularity. Active congestion is associated with left-to-right shunting and is the roentgenographic representation of increased pulmonary flow. Vessels are seen "on end" in the outer third of the lung field. The main pulmonary artery usually is large. Passive congestion occurs with pulmonary venous hypertension and is associated with redistribution of the flow to upper lobes, loss of heart-lung margins due to pulmonary edema, Kerley's B lines, and, eventually, pleural effusions.

With diminished pulmonary flow, the lung fields are underperfused and appear black. The pulmonary peripheral vessels are small and the pulmonary trunk is concave. With long-standing pulmonary underperfusion, bronchial vessels enlarge, and pulmonary flow may appear normal on the chest roentgenogram.

With pulmonary artery hypertension, the proximal pulmonary arteries are dilated and the peripheral arteries are constricted.

Here are some rules of thumb:

1. While right-sided aortic arch may be normal, if associated with heart disease, think of tetralogy of Fallot and truncus arteriosus. With tetralogy of Fallot, cardiothoracic ratio is normal and pulmonary artery segment is concave. With truncus arteriosus, pulmonary flow is increased and cardiothoracic ratio is increased.

2. If pulmonary flow is increased and child is acyanotic, think of ventricular septal defect, patent ductus arteriosus, endocardial cushion defects, and atrial septal defect. If pulmonary flow is increased and the patient is cyanotic, think of transposition of the great vessels, total anomalous pulmonary venous return, and truncus arteriosus.

3. Normal pulmonary flow can be expected in aortic stenosis, isolated coarctation of aorta and pulmonary stenosis. Hypoplastic left heart may have normal flow, active or passive congestion; heart size is increased.

4. A cyanotic child should not have normal pulmonary flow; no acyanotic child with congenital heart disease should have decreased pulmonary flow.

5. Cyanotic congenital heart disease with decreased pulmonary flow think of tetralogy of Fallot, tricuspid atresia (with pulmonary stenosis or atresia) and Ebstein's malformation. Ebstein's malformation produces a globular heart with decreased pulmonary flow. Decreased pulmonary flow and enlarged heart also occur with pericardial tamponade.

6. Don't forget the lung fields. Detection of atelec-

tasis, pneumonia, emphysema, or hypoplasia may help the clinician in evaluation of the underlying cardiovascular problem.

Information gained about cardiac dimensions, gross abnormalities in cardiac configuration, cardiac situs, and pulmonary flow must be correlated with history, physical examination, and other special studies to arrive at the most precise diagnosis.

Pediatric Electrocardiogram

The pediatric electrocardiogram varies with age of the patient. To read the pediatric ECG, the rate and rhythm are determined. The spatial vectors for the QRS complex, the P waves, and the T waves are estimated. The PR interval, the QRS duration, and the QT interval are measured. Measurements are then compared with tables of normal that are arranged according to chronological age.[1] The most common electrocardiographic abnormalities in children are in amplitude of waves, in irregularities of cardiac rhythm, and in interval change.

These are guidelines:

P-wave The P wave amplitude is usually less than 2.5 mm in any lead, duration less than .08 second. Increase in amplitude or duration suggest atrial hypertrophy, which is discussed below.

QRS Complex The duration of the QRS complex usually is less than .10 second. QRS duration tends to increase with age.

Q Waves The Q waves are of minor importance in the pediatric ECG. They represent the initial forces of ventricular (septal) depolarization. A Q wave may be found in leads II, III, AVF, V5, and V6. The duration of a normal Q wave does not exceed .02 second, and the depth does not exceed 4 mm. The exception to this statement is in leads V4R and V1 where Q waves, regardless of amplitude, are abnormal. The presence of a Q wave of any size in leads V4R or V1 is indicative of right ventricular hypertrophy.

VAT The onset of the intrinsicoid deflection or the ventricular activation time (VAT) is the time elapsed from the onset of the Q wave to the peak of the R wave and is assumed to relate to the thickness of the ventricular myocardium. As a rule the ventricular activation time is .03 second or less in lead V1 and .04 second or less in V6. Prolongation of this time is used as an indication of ventricular hypertrophy.

R Prime An R prime in the right chest leads and in lead AVR is a very common finding in the ECG of a child. This may represent either terminal right or left ventricular electrical forces. The taller the R wave, the more likely it is abnormal.

T Wave The T wave is always positive in lead I after the age of 1 month. The T wave is upright in the right precordial leads during the first week of life, but thereafter it is inverted. Changes in the amplitude of the T wave may be seen with electrolyte disturbances, digitalis, metabolic disturbances, and ischemia.

U Wave The U wave is a low amplitude wave that follows the T wave and is found quite frequently in the right precordial leads. There is no known clinical significance for this wave in an otherwise healthy heart, but its amplitude may be increased by hyperkalemia, hypercalcemia, ventricular hypertrophy, hyperthyroidism, and with administration of digitalis and epinephrine.

PR Interval As a general rule, the PR interval is greater than .10 second in duration. It increases with age and is inversely related to heart rate. The PR interval has been shown to fluctuate considerably during the first two years of life, following which it generally remains constant within a given group percentile range.

ST Segment Depression or elevation of this segment less than 1.0 mm is within normal limits. A shift of the ST segment in excess of 1.0 mm may be electrical evidence of digitalis effect, of myocardial injury, or of pericarditis. Prolongation of the ST segment may indicate an electrolyte imbalance such as hypocalcemia.

QT Interval The QT interval is dependent on age and heart rate. The QT interval lengthens with age. Formulae are available for the correction of the QT interval for heart rate, for example, Bazett's formula.

$$QTc = \frac{QT}{\sqrt{R - R}}$$

Rulers and tables are available that enable one to make this correction without doing the mathematical calculations.

Common Electrocardiographic Abnormalities

Electrocardiographic abnormalities in children can be classified as follows: (a) abnormalities in amplitude of the wave formations, (b) abnormalities in rhythm, and (c) abnormalities associated with interval changes. This is, of course, an incomplete classification, but it gives a picture of some of the electrocardiographic abnormalities more commonly encountered.

Abnormalities in Amplitude of the Wave Formations One might reason that if a normal heart releases a certain amount of electrical energy, then a hypertrophied heart might be associated either with an increase in voltage or with an increase in the ventricular

activation time of certain waves, depending on the chamber involved. This is generally true. Also, hypertrophy of a ventricle may be associated with a shift in position of the mean electrical axis (spatial vector). Thus, it is logical that criteria for diagnosis of chamber hypertrophy should include increases in amplitude of waves, increased duration of waves, and deviation of the spatial vector from the normal range. Deviation of the QRS vector to the right is usually associated with right ventricular hypertrophy and to the left is usually associated with left ventricular hypertrophy. If one or more of the criteria listed below are present, the diagnosis of specific chamber hypertrophy can be made.

I. Atrial Hypertrophy
   A. Right Atrial Hypertrophy—Peaked P waves 2.5 mm or more in amplitude, in any lead.
   B. Left Atrial Hypertrophy—(1) Broad and/or notched P waves, particularly in leads, I, II, and V6; (2) P duration greater than 50 percent PR interval; (3) P wave inverted or diphasic with deep (that is, more than 1.5 mm) terminal portion in VI. In the sequence of atrial depolarization, the right atrium is depolarized before the left atrium. Hence, right atrial enlargement is associated with increased voltage in the initial portion of the P wave and is not necessarily associated with a prolonged P wave duration. Left atrial enlargement or hypertrophy is associated with a disturbance in the terminal portion of the P wave and prolongs the duration of this wave.

II. Ventricular Hypertrophy
   A. Left Ventricular Hypertrophy
      1. Voltage increased over leads "looking at" left ventricle: (a) R wave in V6 exceeds upper limits of normal for age; (b) S wave in V1 exceeds limits of normal for age; (c) Sum of R wave in V6 and S wave in V1 (both considered as positive voltages) greater than 45 mm; (d) Sum of R wave in lead II and lead III greater than 45 mm; (e) R wave in AVL or AVF excess upper limits of normal for age; (f) Q wave 4 mm or more deep in leads V5, V6, or V7.
      2. Left axis deviation.
      3. Ventricular activation time prolonged in lead V6. The diagnosis of left ventricular strain can be made if there are associated ST segment or T wave changes or if the QRS and T wave spatial vectors are 180 degrees apart.
   B. Right Ventricular Hypertrophy
      1. Voltage increased over leads "looking at" right ventricle; (a) QR pattern in V4R and V1; (b) R minus S wave in the V1 greater than 15 mm (greater than 20 mm if patient is less than 2 months old); (c) R wave in V1 exceeds upper limits of normal for age; (d) R prime wave in V1 greater than 15 mm (greater than 2 months old); (e) T wave positive in V4R or V1 in patient older than 7 days and younger than 10 years; (f) SV6 deeper than normal for age.
      2. Right axis deviation
      3. Ventricular activation time prolonged in V4R or V1.
   C. Ventricular Hypertrophy
      1. Any of the above criteria for both right and left ventricular hypertrophy.
      2. Large, equiphasic QRS complexes in at least half of limb leads (Katz-Wachtel phenomenon) or of precordial leads.
      3. Presence of definite evidence of hypertrophy of one ventricle with voltage over the other ventricle approaching top-normal values.

Abnormalities in Rhythm

I. Sinus Arrhythmia is commonly encountered and is a normal finding. The PR interval varies, but the QRS complexes, which are normal in configuration, are preceded by a normal P wave and a constant PR interval.

II. Wandering Atrial Pacemaker is identified by beat-to-beat changes in configuration of the P wave, by little or no variation in the PR interval, and by a normal QRS complex.

III. Nodal Rhythm is characterized by a short PR interval and a normal appearing QRS complex. The P wave is initiated in the AV node and spreads retrogradely over the atria. The P wave may occur before, in, or after the QRS complex, referred to as high, mid, and low nodal rhythm respectively. The P wave is inverted in the leads in which it is normally upright; that is, the P axis is to the left and superior.

IV. Atrial Premature Systoles are characterized by (1) a premature QRS complex of normal configuration, (2) a preceding P wave of abnormal configuration, (3) an RR interval between the premature beat and the following QRS complex that is normal, that is, there is no compensatory pause, and (4) a PR interval of different duration than PR interval of a normal sinus beat.

V. Ventricular Premature Systoles are characterized by abnormal QRS complexes of increased amplitude and duration when compared with the normal QRS complexes. The abnormal complexes

are associated with abnormal T wave and ST segments. Following the premature contraction, there is a compensatory pause. That is, the RR interval following the premature beat is prolonged. Ventricular premature systoles are said to be coupled (bigeminy) to the preceding sinus beat if the distance between the two is relatively fixed.

VI. Paroxysmal Atrial Tachycardia is a rapid, regular arrhythmia associated with a heart rate of 200 to 250 per minute. Each QRS complex is usually of normal configuration and is preceded by an abnormal P wave that may be hidden in the preceeding T wave. The PR interval is constant. After conversion of these arrhythmias, evidence of the Wolff-Parkinson-White (WPW) syndrome may be present. The WPW syndrome is characterized by a short PR interval, prolongation of the QRS, and slurring (the delta wave) of the initial portion of the R wave.

VII. Atrial Flutter is a rapid, regular arrhythmia characterized by normal QRS complexes preceded by uniform atrial waves that occur at the rate of 250 to 350 per minute. Atrial flutter waves often have a characteristic "saw-tooth" appearance. Varying degrees of AV nodal conduction frequently give rise to 2:1 or 3:2 atrioventricular block.

VIII. Atrial Fibrillation is characterized by QRS complexes that appear normal but occur with complete irregularity. The waves that indicate atrial activity are small and occur irregularly at rate of 350 or more per minute.

IX. Ventricular Tachycardia is a rapid, regular arrhythmia in which the ventricular complexes are wide and increased in amplitude with associated T wave and ST segment changes. The complexes bear no fixed relationship to the P waves, which frequently are not recognizable. The ventricular rate is usually 150 (plus or minus 30) beats per minute.

X. Ventricular Flutter and Fibrillation consists of broad, notched, and slurred ventricular complexes usually occurring at rates of more than 180 per minute and having the appearance of sine waves. In ventricular fibrillation, the electrical waves are highly disorganized and irregular. P, QRS, and T waves are no longer discernible.

Abnormalities Associated with Interval Change

I. PR Interval
   A. Prolonged
      1. First degree heart block (first degree atrioventricular block) is present if the PR interval exceeds the limits of normal for age and rate. This may be normal or associated with certain disease states. Increased vagal tone also prolongs the PR interval.
      2. Second degree heart block (second degree atrioventricular block): some P waves are not conducted to the ventricles. Most commonly, in pediatrics, second degree AV block is associated with digitalis intoxication. The ECG is often characterized by periods of progressive prolongation of the PR interval for several beats and terminated with a P wave, which is not conducted. This is known as the Wenckebach period or phenomenon. Other types of second degree AV block may be seen with an atrial rate twice ventricular rate (2 to 1 AV block) or with an atrial rate 3 times ventricular rate (3 to 1 AV block), etc. That is, every second or third P wave is conducted. The PR interval preceding each QRS complex is relatively constant in length.
      3. Third degree heart block (third degree atrioventricular block). In third degree or complete heart block, atrial impulses are not conducted through the AV node. There is independence of the atrial and ventricular beats. The ventricles are driven by a nodal or ventricular pacemaker. The atrial rate is more rapid than that of the nodal or ventricular pacemaker. On the ECG, P waves can be seen to "march through" the QRS complexes without altering the rhythm of the ventricles. The ventricular rate is 40 to 50 beats per minute.
      4. AV dissocation: the atrial beats are not transmitted to the ventricle because of the presence of a nodal pacemaker with a rate greater than that of the SA node. Thus, the ventricular rate is usually in excess of 100 beats per minute. The dissocation may be incomplete; that is, a sinus beat occasionally may be transmitted (ventricular capture).
   B. Shortened: (1) Coronary sinus rhythm or an atrial pacemaker located other than at the SA node; (2) WPW syndrome, see above; (3) Magnesium deficiency; (4) Cardiac glycogen storage disease.

II. QRS Duration, Prolonged
   A. Bundle branch block or aberrant intraventricular conduction.
   B. WPW syndrome
   C. Ventricular pacemaker

III. QT Interval
   A. Prolonged: (1) Hypocalcemia (prolonged QT interval due to prolonged ST segment, T wave appears relatively normal); (2) Hypokalemia (prolonged QT with low, wide T waves, depressed ST segment, U wave may be present); (3) Myocardial disease; (4) surdo cardiac syndrome (prolonged QT and deafness, sudden death)
   B. Shortened: (1) Hypercalcemia; (2) Digitalis (ST segment usually depressed also); (3) Hypothyroidism, especially with short ST segment that blends with the T wave; (4) Quinidine and procaineamide (also produce lengthening of the QRS interval).

To read and understand pediatric electrocardiograms (1) measure the variables mentioned above, (2) keep in mind the wide range of normal in different age groups, (3) always check tables of normal values before stating that certain intervals or amplitudes are abnormal, and (4) decide which pattern of electrocardiographic abnormality the abnormal variables represent.

Holter Monitoring

The technique of ambulatory electrocardiographic monitoring has been available since 1961 when it was described by Holter.[2] Electrocardiograms are recorded on magnetic tape during a 24-hour period and subsequently are analyzed. The major value of Holter monitoring is to detect intermittent arrhythmias, to relate arrhythmias to daily activities, and to quantitate arrhythmias and the effect of therapy. A major disadvantage is that the event for which you are recording may not occur during the period in which the patient is monitored. This is particularly frustrating when the arrhythmia is sporadic. If one suspects arrhythmia and ambulatory monitoring has been unrevealing, simple counting of the pulse, direct telephone transmission of ECG, or use of an event recorder (tape activated only when certain parameters are exceeded) are alternate approaches.

Stress Testing

Stress testing is useful for the identification of patients with congenital or acquired heart disease, for assessment of cardiovascular status in patients with heart disease and in assessment of training in athletes.

The patient is placed on treadmill or bicycle ergometer and exercised until further increases in work produce no change in heart rate, until a theoretical maximal heart rate is achieved, until patient becomes fatigued, or until patient develops symptoms or electrocardiographic findings.

Factors that alter cardiac response to exercise include the following: (1) the type and severity of the malformation; (2) the impairment in cardiac output or stroke volume; (3) the functional status of the myocardium; (4) the arterial oxygen saturation; (5) the systemic and pulmonary blood pressures; (6) the presence of cardiac rhythm disturbances; (7) parental attitudes; (8) the child's self-image, and (9) the general physical condition of the patient.

Sports participation is a natural part of the normal maturational process. The goal of exercise testing is not to prohibit sports participation but to allow the child to participate safely.

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Consultation

The Faculty's radio program on WBJC-FM (91.5 mHz on your dial)
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May 29	**Sexually Transmitted Diseases**	Edward Sawada MD Edward Campbell MD
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June 26	**Ears, Noses, and Throats**	Michael Holliday MD

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An introductory synopsis/abstract of approximately 100–150 words is required.

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Aftermath of Pediatric Heart Surgery

LANGFORD KIDD MD

Dr. Kidd is Director, Division of Pediatric Cardiology, the Johns Hopkins Hospital, Baltimore.

The first patient to go home after successful surgery for congenital heart disease (ligation of a persistent ductus arteriosus) was discharged by Gross and Hubbard in 1938. Major milestones occurred six years later when surgery for coarctation of the aorta began and the first blue baby operation was performed by Blalock and Taussig. Surface cooling with moderate hypothermia allowed brief circulatory arrest, which paved the way for open heart surgery to begin in the early 1950s. The advent of the heart-lung machine and refinements with deep hypothermia opened the field further, and now hundreds of children are leaving hospitals in Maryland after heart surgery each year.

In the early days of heart surgery, survival after surgery was considered a cure. However, some patients did not have normal hearts following surgery. Some procedures (such as Blalock-Taussig anastomosis) are by definition palliative; other procedures (such as aortic valvotomy) that might be considered corrective surgery are probably only palliative. The addition of artificial valves, conduits, and suturing materials in these hearts makes them certainly abnormal. The major question then is, how do these patients do after discharge from hospital?

1. **Was the surgery effective?** A number of physical signs can be helpful in this regard. For example, there should be a continuous murmur after a Blalock-Taussig anastomisis. There should be no murmur following a ductus ligation. However, a good proportion of children will continue to have murmur following ventricular septal defect closure; this occasionally is due to a tiny residual ventricular septal defect, but more often it is due to roughness in the right ventricular outflow tract. Following correction of tetralogy of Fallot, children often have both systolic and early diastolic murmurs from the same area.

2. **Is the conducting system intact?** Complete heart block as a residuum of ventricular septal defect closure is rare but can occur on occasion. Right bundle block can advance postoperatively, with the addition of left anterior hemiblock, to complete heart block. The presence of premature ventricular contractions postoperatively should be watched for.

3. **Has vascular resistance fallen to normal?** If pulmonary hypertension has been present (for perhaps as short a period as two years), pulmonary vascular resistance may fail to fall following successful closure of the ventricular septal defect. Pulmonary vascular damage probably occurs at an earlier age in patients with transposition of the great arteries and in patients with Down's syndrome. On the systemic side of circulation, residual hypertension has been found following successful coarctectomy in 10 to 20 percent of patients.

4. **What is the state of the myocardium?** Myocardial preservation during open heart surgery has greatly improved. There often has been a burden on myocardium before heart surgery; some patients do not reap the expected or anticipated improvement in myocardial function.

5. **Is the patient psychosocially adapted?** It is important for pediatricians and cardiologists to work together to ensure that patients following successful heart surgery enter life with clear expectations and are encouraged to lead an unhampered existence. The possibility of bacterial endocarditis must be discussed; in some cases (for example, for patients with conduits), the possibility of further surgery should be realistically assessed.

The majority of these patients are fit and healthy and may expect to lead normal lives. Some are cured (patent ductus arteriosus, arterial septal defect, pulmonary stenosis). Others are not. As they enter adult life, however, they face fresh hazards. Internists must be aware of the residual problems a postoperative child and young adult will have and be prepared to help when ischemic heart disease, essential hypertension, and chronic obstructive lung disease add burdens.

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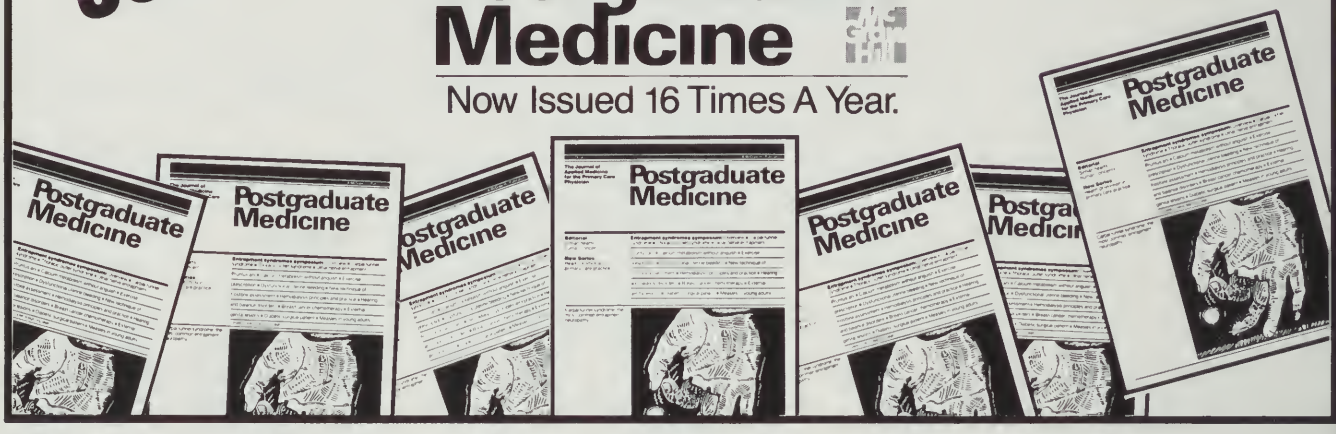
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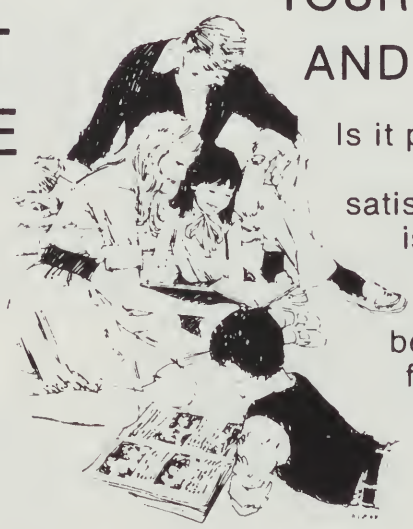
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Child Abuse and Neglect: Sexual Abuse of Prepubertal Children

CHARLES I. SHUBIN MD

The reported incidence of child sexual abuse has risen from 1,020 cases in 1982 to a projected 1,800 in 1984, an increase of almost 80 percent. Certainly some of this increase is the result of increased awareness leading to increased reporting, but there also could be a real increase in incidence.

Dr. Shubin is Chief of Pediatrics, Lutheran Hospital of Maryland; Assistant Professor of Pediatrics, the Johns Hopkins University School of Medicine, University of Maryland School of Medicine; and Chairman, Governor's Task Force on Child Abuse and Neglect.

The definition of child sexual abuse in Maryland Law (Article 27, Section 55A(a)(4)) is:

> Any act that involves sexual molestation or exploitation of a child by a parent or other person who has permanent or temporary care or custody or responsibility for supervision of a child. Sexual abuse includes, but is not limited to:
> a. Incest, rape, or sexual offense in any degree;
> b. Sodomy; and
> c. Unnatural or perverted sexual practices.

Previously, abuse by caretakers of children usually was within the family and/or home environment, but it has become apparent that such abuse can and does occur in other settings: nursery schools, regular schools, day care facilities, and day camps. Should the sexual abuse be perpetrated by other than a caretaker, then the sexual offense and rape laws would apply. Since the above definition includes exploitation as well as molestation, pornography and other inappropriate but physically noninjurious sexual activities would be considered sexual abuse under the law. A caretaker who sexually abuses (as defined above) a child is guilty of a felony and, on conviction is subject to imprisonment in the penitentiary, not exceeding 15 years.

The following discussion will focus on sexual abuse of the prepubertal child.

Presentations

A child who has been sexually abused may present to the physician or other health care providers in a variety of ways (Table 1).

Sexually Transmitted Diseases The finding in a prepubertal child of disease that is transmitted sexually means, until proved otherwise, that child has been sexually abused. Such diseases currently include gonorrhea, syphilis, condyloma acuminata (veneral warts), and Herpes Type II. Some sexually transmitted diseases are also transmitted nonsexually (such as chlamydia, trichomonas, Hepatitis B, and Herpes Type I) and should arouse suspicions of sexual abuse. In such situations, further history should be obtained, additional physical indicators sought, and appropriate laboratory studies performed (cultures for gonorrhea, serology for syphilis, possibly cultures for chlamydia, and Herpes).

Despite the theoretical possibility of transfer of sexually transmitted diseases by fomites or other nonsexual means,[1] the presence of one or more of these infections in a prepubertal child is almost always the result of sexual abuse.

Revelations by the Victim (or Others) With increasing frequency, child sexual abuse has been presenting as revelations by the victim, either spontaneously or upon questioning. Since there is no way a young child, with the concrete thinking characteristic of this age group, can fabricate or fantasize an experience that represents adult sexual activity unless the child personally experienced the activity, such revelations virtually always are accurate and thus should be believed. Whenever a situation suspicious for child sexual abuse presents, the child must be given an appropriate opportunity to reveal what has been done to him or her and by whom. The number of times the child has to tell his or her story should be kept to the absolute minimum (preferably only once) by coordinating the questioning of the health care provider, the Department of Social Services investigator, the police, and the States Attorney. Where appropriate, anatomically correct drawings and/or dolls should be used to permit the child flexibility in how the story is told.

Sometimes one victim will reveal sexual abuse that is occurring or has occurred to another victim (or victims), such as in a group-care setting. Such revelations should be believed and taken seriously, especially with the younger preschool child.

Occasionally an abuser, spontaneously, under interrogation or while in therapy will reveal that he or she has abused specific children, and such revelations must be followed up. When an abuser makes such a revelation in a therapeutic setting where the therapist has had no contact with the victim(s), there is some controversy as

Table 1. Presentations of Sexual Abuse

1. Sexually transmitted diseases
   - Gonorrhea, Syphilis, Condyloma Acuminata, Herpes Type II
2. Revelations by victims or others
   - Confessions by abusers
   - Revelations by other victims or witnesses
   - Revelations by child victims, spontaneous or on questioning
3. Behavior presentations
   - Sexual behavior inappropriate for child's developmental level
   - Nonsexual behavior, depression, aggression, school performance deterioration, running away from home

to whether the therapist is required to report the situation. Section 5-903 of the Maryland Family Law Article requires any such professional who

> contacts, examines, attends, or treats a child *AND* (emphasis mine) who has reason to believe that the child has been subjected to abuse shall

make a report, thus requiring the professional both to contact the child AND to have reason to believe the child has been abused before the mandate to report is applicable. However, Section 5-704 of the same article states that such a professional who

> contacts, examines, attends, or treats a neglected child *OR* (emphasis mine) who has reason to believe that the child is a neglected child shall

make a report. Neglect is defined in Section 5-701 (g)(2) of the same article:

> the failure of the child's parents, guardian or custodian to give proper care and attention to the child and the child's problems under circumstances that indicate that the child's health or welfare is harmed or threatened thereby.

Clearly this includes sexual abuse of the child. It appears that revelations of an abuser to a therapist about abuse of a child are required to be reported by the therapist under Section 5-704 of the Family Law Article, thereby leading to an investigation with the provision of necessary protection, assistance, and therapy to the child(ren) involved.

Behavior Presentations Virtually any aberrant behavior by a child can be a manifestation of the child having been sexually abused, and a high index of suspicion must be maintained if such children are to be diagnosed correctly. Types of behavior that may be indicative of sexual abuse are listed in Table 2. The possibility of the child having been sexually abused must always be kept in mind when evaluating or treating childhood behavior problems.

The Interview

The first task in interviewing a sexually abused child is to establish rapport in a situation comfortable to both the child and the interviewer. To prevent the child from having to repeat the events of the abuse, arrangements should be made to have those other professionals who need to hear the child's story present during the history taking. Sometimes this is not possible and/or not appropriate, although Maryland Law currently requires a combined investigation of suspected sexual abuse by the Department of Social Services, the police, and the States Attorney.[2]

Table 2. Behavioral Presentations of Child Sexual Abuse

Precocious sexual interest and/or behavior
Involvement with pornographic materials
Acting-out behaviors, that is, running away
Deteriorating school performance
Poor peer relationship
Seductive behavior
Depression, decreased self-esteem
Aggressive behavior, violent acts
Antisocial behavior such as stealing

The history of the incident(s) should be obtained from the child directly, using terms the child understands. It frequently is helpful to use anatomically correct drawings and/or dolls to get the child to indicate the parts of the anatomy involved, the names of which may be different for the child than for adults. History should be obtained from anyone who has information concerning the situation. This includes other members of the household, social workers, other health professionals, teachers, day care workers, or anyone who may have information that could assist in elucidating what actually happened.

It is important to go through a complete medical history, including a history of past illnesses, especially any history of past similar incidents. Questions concerning the child's allergy to medications are necessary in circumstances where treatment of the child for possible sexually transmitted disease is considered. A complete review of systems is indicated, paying special attention to the genitourinary tract. It is important to ascertain the psychological status of the child. As many incidents are repetitive and occur over extended periods of time, it is important to determine the child's function in school, in his/her family, and with his/her peers.

A critical consideration in taking the history from the child is to remember that once the child has "blown the whistle" on the abuser, he or she may be in immediate danger of further abuse or even death. It is imperative that the examiner and other professionals involved be in a position to protect the child with immediate placement in a safe environment, if this is needed.

Complete documentation of the history (as much as possible in the exact words used by those giving it) should be done in a clear, legible manner as this document frequently is used in the investigation, the legal process for protecting the child, and/or the prosecution of the abuser.

The Physical Examination

As this part of the evaluation of the sexually abused child is frequently necessary for court, careful documentation of the findings, both positive and negative, with legible notes and photographs is advisable. The use of an instant camera can be invaluable in providing

this type of evidence. Such photographs need to be identified clearly with the name of the child, the name of the photographer, the date, and the medical record number, if any. Such photographs should be attached to the medical record using staples, as most tapes will deteriorate over time. The photographs thereby become part of the permanent medical record of the child. In Maryland, it is not necessary to get permission to take photographs of abused children in such situations.

Two basic principles to be followed in the physical examination of the sexually abused child are: first, do a complete physical examination; second, the examination should be as nontraumatic to the child as possible. Because many of these children have been physically abused in addition to having been sexually abused, it is important to do a complete physical examination. Inspection of areas that have been sexually abused is more acceptable to children in the context of a complete examination than as an isolated scrutiny of the abused parts, which could be construed by the child as comparable to the original abuse or worse.

It is important to assure privacy and concern for the child's modesty, and to provide a same-sex chaperone in the situation where the examination is being performed by a professional of the opposite sex. Whenever there is evidence of physical abuse or where the child is less than three years old, an occult trauma x-ray survey is recommended as this may reveal evidence of previous bony injuries that may not be obvious in the physical examination.

It should *never* be necessary to force an examination of the genital area. The vast majority of the time this part of the examination can be done atraumatically by putting it in the context of the complete physical. Having the child relax, not on an examining table but in the lap of a trusted adult, is frequently helpful for a preschool child. The child's willingness to relax and permit examination of the perineum is not a reliable indicator of the child's having been abused, rather the child's resistance to such an examination may suggest the child has been sexually abused.

In those children in whom such an examination is not possible without force, the use of some form of sedation, that is, so-called "lytic cocktail" (meperdine, two milligrams per kilogram; promethazine, one milligram per kilogram; and chlorpromazine, one milligram per kilogram, mixed in one syringe and given intramuscularly) is recommended. In very rare situations, it is necessary to use general anesthesia to adequately examine a sexually abused child.

Recently, new interpretations of findings on examination of the genital and anal areas of sexually abused children have permitted corroboration of histories far more often than previously.[3] In the female, genital sexual injuries can be differentiated from normal anatomy or accidental trauma. This can be done with an understanding of the functional anatomy of this area and a knowledge of the appearance of injured tissue. The external genitalia of the young girl can be divided into anterior and posterior sections by imagining the numbers of a clock face with the 12 anterior (symphasis pubis) and the 6 posterior (toward the anus) so that the introitus is in the center of the clock face. The anterior section would be above the 9 o'clock and 3 o'clock indicators and the posterior section would be below.

Tissue comprising the anterior section is rather tightly attached to the pubic rami and is involved in accidental (straddle-type) injury because of the relative immobility and position of that section of the genitalia relative to the bony pelvis. The posterior section is essentially suspended by the internal muscular supports of the pelvic organs, mostly the levator sling. Because of this suspended structure, this tissue can move considerably and essentially is not injured accidently. However, during sexual activity, the vagina must be entered with a movement of the penetrating object posteriorly, so sexual molestation would cause injury to the posterior section of the genitalia. As full penetration of the vagina of small girls is very rare, these injuries are of a more subtle nature, comprising stretching and/or tearing of the hymenal or perihymenal tissue, again posteriorly (that is, below the 9 o'clock–3 o'clock line). These injuries, once healed, leave permanent scarring of this tissue which is apparent on close observation (with or without a culdoscope) as white scar tissue, distortion (usually asymmetrical) of the tissue, or both. The finding of such scars in the posterior section of the female genitalia is essentially diagnostic of previous sexual abuse with attempted penetration.

Another useful finding in the examination of the prepubertal girl is the size of the introital opening, which is normally no greater than 1 cm. in diameter and usually much less than that, especially in the younger child. An introital (actually hymenal) opening of greater than 1 cm. would indicate stretching of the introitus, indicating probable sexual abuse.

In both males and females, the anal orifice can demonstrate findings indicative of attempted or actual penetration. These findings are of similar scarring as described above, except there is no anterior/posterior discrimination of accidental versus sexually abusive injury. When the anus is dilated by the passage of a large stool, the stretching occurs from inside, while sexually abusive penetration is from the outside. The injury in passage of a large stool is thus internal (anal fissure or tear) involving the mucosal surface, while penetrating injury is more external, usually at the skin-mucosal border.

The above examinations can be done atraumatically and without invasion of the child (such as use of a speculum) in the vast majority of instances. All that is usually needed is a relaxed patient, a supportive, understanding examiner, and a bright light. Specimens for laboratory studies, as described in the next section, usually can be obtained relatively atraumatically using a flexible swab and sterile saline, if the tissue is dry.

Laboratory Evaluation

The laboratory evaluation of the prepubertal child suspected of having been sexually abused would include (*as indicated*): smears and cultures for gonorrhea, serology for syphilis, cell cultures for chlamydia, and/or cultures for Herpes Virus with immuno-identification of Type I or II. Whenever penetration or attempted penetration is strongly suspected, gonorrheal and syphilis testing should be done. Chlamydial cultures, whenever readily available can be included. Lesions suspected or Herpes infection should be cultured for that virus, specifically requesting immunologic testing (ELISA or similar) for the type of Herpes virus found. Other less specific tests can be done, such as microscopic examination of a wet preparation of vaginal or vulvar secretions for trichomonas.

In the asymptomatic male, either a child who has been abused or a suspected contact of an abused child, where there is no urethral discharge, a urine specimen (either a first-voided specimen or if that is not possible, a randomly voided specimen) spun in a centrifuge can reveal evidence of gonorrhea that would not be obtainable any other way. If white blood cells are seen in the spun urine sediment of an asymptomatic male, a gram stain of such a sediment frequently will be diagnostic of gonorrhea. The culture of the urine sediment also can reveal gonorrhea. This approach is far more acceptable than deep wire-swab cultures of the male urethra.

Responses to the Sexually Abused Prepubertal Child

It is most important to believe the sexually abused prepubertal child! As mentioned previously, children in this age group virtually never fabricate descriptions of having been sexually abused. They can, however, be coached to tell a story that an adult (such as a parent fighting over custody and/or visitation) wants them to tell. Such stories, listened to carefully and combined with private interviewing of the child, can be distinguished from real experiences by indirect and detailed questioning to which the child cannot respond. Coached stories usually are identifiable because the child's concrete thinking does not permit accurate responses to questions he or she has not been prepared for. The child should also be asked to describe how the abuse felt, because a coached child could not answer this.

Appropriate responses include arranging for protection of the child, reporting to the required agencies, assisting in the legal process these children usually have to go through, and referring the child (and usually the family) to indicated treatment resources.

Reporting

Section 5-901 of the Maryland Family Law Article requires reporting of child sexual abuse. Section 5-904 of the same Article now requires

> within 24 hours after receiving the report of suspected abuse, the local department or the appropriate law enforcement agency shall
> 1. See the child;
> 2. Attempt to have an on-site interview with the child's caretakers; and
> 3. Decide on the safety of the child, wherever the child is, and of other children in the home.

Additionally, further new language requires that the agencies responsible for investigating child sexual abuse, including the local department, the appropriate law enforcement agencies, and the local State's Attorney shall implement a joint investigation procedure for conducting joint investigations of child sexual abuse. Section 5-905 further states:

> The joint investigation procedure shall
> a) include appropriate techniques for expediting validation of child sexual abuse complaints;
> b) include investigation techniques designed to:
> 1. decrease the potential for physical harm to the child; and
> 2. decrease any trauma experienced by the child in the investigation and prosecution of the case; and
> c) establish a training program prior to July 1, 1985, for personnel involved in the investigation or prosecution of child sexual abuse cases.

The Governor's Task Force on Child Abuse and Neglect proposed the above changes in the law to assure an appropriate and timely response to the sexually abused child. It is hoped these improvements will make professionals who see such children confident of the response their reporting these cases will get, and thus be more willing to report than heretofore.

Protecting the Child

Once a child has "blown the whistle" on a sexual abuser, that child is at immediate and severe risk of harm from the abuser (or others) and must be assured protection. Reporting such situations to the local Department of Social Services and especially to the police

should provide some protection, but resources for immedite protective placement of children are extremely limited and may not be available when needed. In such cases, admission to the hospital may be the only way to assure the child's protection and should be arranged, even though there is no specific medical indication for admission. While the new section 5-910 of the Family Law Article provides for "emergency medical treatment" to be paid for, such treatment is only

> (i) to relieve any urgent illness or life threatening health condition; or
> (ii) to determine the nature or extent of any alleged injury or health condition.

This emergency medical treatment does not include

> (i) nonemergency outpatient treatment; or
> (ii) periodic nonemergency health care.

Admission of sexually abused children to the hospital usually would *not* meet the above criteria for payment for such services, and as criteria for admission under most third-party payment regulations also usually would not be met, such admissions would not be reimbursed. An understanding and committed hospital administration is needed to accept such admissions. If significant numbers of such admissions occur in the future, with substantial financial losses by the hospitals involved, additional changes in the law will be needed to provide for payment for such admissions.

The legal process in sexual abuse cases was described in "Child Abuse and Neglect: Legal Implications."[4] Many such cases also are involved in divorce and disputed custody and/or visitation proceedings. The new Section 9-101 of the Family Law Article now provides

> In any custody or visitation proceeding, if the Court has reasonable grounds to believe that a child has been abused or neglected by a party to the proceeding, the Court shall determine whether abuse or neglect is likely to occur if custody or visitation rights are granted to the party.

Additionally

> unless the Court specifically finds that there is no likelihood of further child abuse or neglect by the party, the Court shall deny custody or visitation rights to that party, except that the Court may approve a supervised visitation arrangement that assures the safety of the child.

The above new provisions were proposed by the Task Force on Child Abuse and Neglect with sexual abuse situations specifically in mind, because many such cases are incestuous and frequently either lead to or are part of divorce, custody, and visitation proceedings. Health care providers may, of course, become involved in these proceedings because of their medical findings, but even if obvious findings of sexual abuse are present, it is still necessary for the child (or others, if possible) to testify as to who the abuser was and what he/she actually did to the child.

Children are frequently intimidated when testifying in sexual abuse cases, and many times the fear of further harm to a victimized child will affect the legal tactics employed. It is possible that prosecution may not be attempted or that an unfavorable settlement may be agreed to in order to spare the child the ordeal of testifying in open court in direct confrontation with the abuser. Because of these situations, the Task Force proposed legislation for consideration by the Governor and the 1985 session of the General Assembly that would buffer and protect the child whose testimony is needed in child sexual cases.

Referring for Treatment

There is increasing evidence that children who have been sexually abused have emotional and psychological scars far worse than physical scars they might have. In addition, many cases are intrafamilial (incestuous or with a family member at least indirectly involved), and the child's abuse is either a result of, or results in, serious psychological and emotional problems of other family members. Therefore, it is imperative such children and their involved family members be referred for appropriate treatment. The demand for such treatment has increased markedly, parallel to the increased awareness and reporting of sexual abuse occurrences, but the resources necessary to respond adequately to this demand are not yet fully developed. It may be difficult to find an appropriate treatment resource for an individual child and/or the involved family.

Types of treatment programs that have shown at least some effectiveness include traditional individual psychotherapy, group therapy (professional and self-help), specific treatment programs for sexual offenders (including chemical castration programs), and support programs run by the involved agencies (for example, The Sexual Abuse Treatment Program of the Baltimore City Department of Social Services). Since availability of such programs and therapists in a given locality varies considerably, consultation with local professionals or involved volunteers is usually the best way to determine the appropriate referral.

Prevention

Unfortunately, even if adequate and effective treatment resources were available, treatment of child sexual abuse is not completely effective and is very expensive. A more cost-effective way of dealing with the problem would be prevention or at least very early intervention to obstruct the usual repetitive pattern.

To effectively prevent child sexual abuse, we must

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educate our children as to what is and is not acceptable sexual activity or touching. We must not interfere with healthy touching between adults and children that is a necessary part of growing up, but we must prevent touch that makes the child uncomfortable or sexual activities inappropriate for the child's developmental level. Additionally, we must believe what our children tell us and convince them that we will believe them if they tell us of uncomfortable touching or inappropriate sexual experiences. We must teach them there are some secrets adults want children to keep that cannot be kept but must be told to a trusted and helping adult.

Only when we achieve the above will the problem of sexual abuse of the prepubertal child begin to diminish and the approaches to such children described here no longer be needed.

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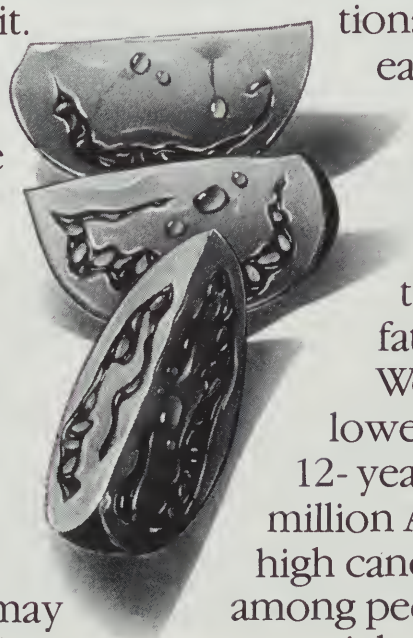
Foods that may help reduce the risk of gastrointestinal and respiratory tract cancer are cabbage, broccoli, brussels sprouts, kohlrabi, cauliflower.

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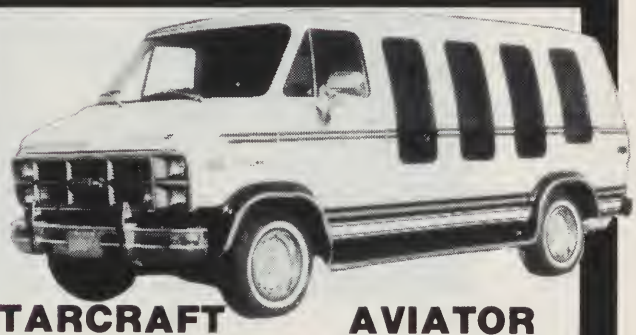
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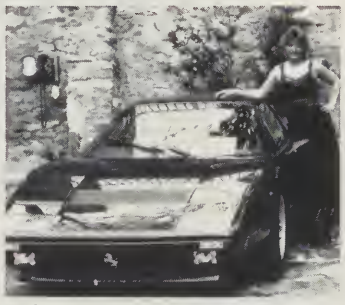
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Discipline Commission Action

In the Matter of
Rhonda Fishel MD
Before the Commission
on Medical Discipline
of Maryland

Order Terminating Probation and Reinstating License

By order dated December 21, 1982 (the "1982 Order") the Commission on Medical Discipline (the "Commission") found Rhonda Fishel MD (the "Respondent") guilty of drug abuse pursuant to Maryland Code Annotated (recodified as 14-504(9) of the Health Occupations Article). The Commission revoked the medical license of respondent and placed her on probation subject to certain conditions (the "Conditions of Probation"). The Order further provided that after two (2) years from the date of the Order, if Respondent complied satisfactorily with the Conditions of Probation, the Commission would entertain a petition for termination of Respondent's probationary status and reinstatement of her medical license without any condition or restriction. On December 30, 1984 Respondent petitioned the Commission for reinstatement of her license to practice medicine in Maryland without any conditions or restrictions. At its meeting on January 29, 1985 the Commission reviewed Respondent's petition for reinstatement. Based on its review of the petition the Commission determined that Respondent had fulfilled the Conditions of Probation contained in the 1982 Order.

Findings of Fact

The Commission finds that Respondent has satisfactorily complied with all the Conditions of Probation imposed by the Commission's 1982 Order.

Conclusions of Law

The Commission concludes, as a matter of law, that it is appropriate to terminate Respondent's Conditions of Probation and to reinstate her license without any condition or restriction.

Order

Upon the foregoing Findings of Fact and Conclusions of Law, it is this 19th day of February 1985, by a unanimous vote of a quorum of the Commission:

ORDERED that effective as of the date of this Order the Conditions of Probation imposed upon Respondent's practice of medicine by the Commission's 1982 Order are hereby TERMINATED and of no further force and effect; and be it further ORDERED that Respondent's license to practice medicine in the State of Maryland be REINSTATED without any condition or restriction whatsoever.

HILARY T. O'HERLIHY MD, **Chairman**
Commission of Medical Discipline of Maryland

In the Matter of
George Hebeka MD
Before the Commission
on Medical Discipline
of Maryland

Order Terminating Probation and Reinstating Medical License

By Order dated July 19, 1982 (the "1982 Order") the Commission on Medical Discipline of Maryland (the "Commission") found George Hebeka MD (the "Respondent") guilty of violation of §14-504(b) of the Health Occupations Article of the Annotated Code of Maryland. The Commission suspended the medical license of Respondent, stayed the suspension, and placed him on probation for 2 years subject to certain conditions (The "Conditions of Probation").

Findings of Fact

The Commission finds that Respondent has satisfactorily complied with all the Conditions of Probation imposed by the Commission's 1982 Order.

Conclusions of Law

The Commission concludes, as a matter of law, that it is appropriate to terminate Respondent's Conditions of Probation and to reinstate his license without any condition or restriction.

Order

Upon the foregoing Findings of Fact and Conclusions of Law, it is this 29th day of January 1985, by a unanimous vote of a quorum of the Commission:

ORDERED that effective as of the date of this Order the Conditions of Probation imposed upon Respondent's practice of medicine by the Commission's 1982 Order are hereby TERMINATED and of no further force and effect; and it is further

ORDERED that Respondent's license to practice medicine in the State of Maryland be REINSTATED without any condition or restriction whatsoever.

HILARY T. O'HERLIHY MD, **Chairman**
Commission on Medical Discipline of Maryland

On instruction of the Council of the Medical and Chirurgical Faculty of the State of Maryland, "Findings of Fact, Conclusions of Law, and Order" will be published in the Maryland Medical Journal.

In the Matter of
Gerald A. Miller MD
Before the
Commission on
Medical Discipline
of Maryland

Findings of Fact, Conclusions of Law and Order

Preliminary Statement

Upon certain information coming to the attention of the Commission on Medical Discipline (the "Commission"), the Commission requested that the Peer Review Committee of the Medical and Chirurgical Faculty of the State of Maryland ("Med Chi") investigate the practice of Gerald A. Miller MD ("Respondent"). After the investigation, and the receipt of Med Chi's report the Commission determined to charge Respondent with violation of Sections 14-504 (3), (4), (12) and (18) of the Medical Practice Act, Health Occupations Article, Annotated Code of Maryland.

Findings of Fact

Based on the information known and available to it the Commission finds that:

1. At all time relevant to the case Respondent was a physician licensed to practice medicine in the State of Maryland;

2. At all times relevant to the case Respondent limited his practice to the practice of ophthalmology;

3. On November 17, 1978, Respondent performed a lens implant on Patient A* which required a written informed consent to be signed by Patient A prior to the operation;

4. Respondent did not have patient A sign an informed consent prior to her operation. After the operation Respondent had Patient A sign a five (5) page document that he stated was needed for the lens manufacturer. Patient A signed the last page of this document but neither Patient A nor her husband read the document, which was a standard informed consent agreement. Thereafter, without the knowledge of Patient A, Respondent admittedly backdated the document to November 17, 1978;

5. As a result of this incident a complaint was made to the Commission; subsequently, Respondent's practice was reviewed by a Peer Review Committee of Med Chi, which consisted of three (3) ophthalmologists (the "Committee");

6. Upon its initial review in June of 1983 the Committee identified the following problem areas in Respondent's practice:

a. Poor clinical judgment and faulty decision making abilities;
b. Grossly inadequate records;
c. Inappropriate and unnecessary surgery;
d. Inappropriate postoperative evaluation and care;
e. Inadequate general ophthalmologic care;
f. Poor utilization of consultants;
g. Scope of practice exceed Respondent's training and experience; and
h. Excessive work load.

7. Respondent was apprised of the results of the Committee's review and attempted to correct the deficiencies in his practice as identified by the Committee;

8. A second Peer Review was conducted in October 1984 upon request of the prosecuting attorneys and counsel for Respondent to determine what if any progress had been made by Respondent;

9. Although the Committee found that Respondent had made some improvements, most notably in the area of record keeping, it still reported that Respondent's practice was deficient; and

10. As a result of the second Peer Review Report Respondent agreed to enter into the following consent order, which is based on the recommendations of the Committee.

Order

Based on the foregoing Findings of Fact, Conclusions of Law, it is this 29th day of January 1985, by a majority vote of those members of the Commission on Medical Discipline (the "Commission") considering this case it is hereby ORDERED that the license of Respondent, GERALD A. MILLER MD, to practice medicine shall be SUSPENDED unless Respondent complies with the following conditions:

1. *Record Keeping*

a. General: Each patient file shall be kept separately and each patient file shall contain the necessary forms which shall be legible and complete as more fully described below. Each patient shall have a best corrected visual acuity for each eye every visit and upon every visit there shall be recorded a diagnosis or impression and disposition for each patient. The pertinent positive and negative findings which lead to the diagnosis and disposition shall be recorded on each patient;

b. Initial Visits: Respondent shall improve his record keeping for initial visits by utilizing form A attached hereto and performing at minimum the following examinations and obtaining the following information. List all ocular complaints, record a complete medical history, list all medications the patient is presently taking and any allergies to medications, record the name of the patient's local medical doctor, the prescription for present eye glasses, visual acuity in both eyes with and without current prescription, best corrected visual acuity in both eyes with refraction, external ex-

* Patients names have been coded to protect the patients confidentiality.

amination, pupils, extraocular movements and muscle balance, slit lamp examination for the right and left eye, fundus examination, with name of dilating agent, and a clear description of the fundus, i.e. the optic nerve, macula, peripheral retina and vessels. All medications and/or eye drops given in the office during the examination should be listed. All patients over 40 should be given an applanation tonometry examination. All patients for whom glasses are prescribed should have the prescription recorded on the patient's records and any and all optometrist notes in the patient records should be countersigned by Respondent. The date the patient is told to return to the office should be noted on the record. Finally a diagnosis or clinical impression together with a disposition for each diagnosis MUST be recorded;

c. Follow-Up Visits: Depending upon the initial diagnosis Respondent shall utilize a follow-up form designed for that purpose if possible, recording all necessary information, and performing any necessary examinations making certain that there is a diagnosis and/or clinical impression together with a disposition for each diagnosis, noting on the record any medications prescribed or stopped, and any recommended date to return to the office;

d. Glaucoma patients: In addition to the above all glaucoma patients shall be seen on bi-annual basis. An applanation tonometry on each eye shall be listed for each visit, together with any medications being taken. The optic nerve in all glaucoma patients shall be described each visit;

e. 1) All operative patients: A copy of an informed consent for operative patients which has been dated, signed, and witnessed by a third party must be kept in each patient's chart. A typed operative report from the hospital must be kept in the patient office record. Notations of any postoperative visits and findings must be noted together with recommended dates to return to the office together with the name, dosage, and frequency of all medications and drops that all postoperative patients are taking with the termination point.

2) Cataract Patients: In addition to the above Surgery patients: With patients posted for cataract surgery a pin hole vision examination must be recorded. A description of the optic nerve, macula, and peripheral retina of both eyes must be recorded. If a fundus view is not possible a note about the status of entopic imagery or ultrasound must be reported. The corneal endothelium of both eyes must be described. The type of cataract surgery planned must be noted together with the type of lens to be used and the hospital at which the surgery will be performed.

f. Hospital Records: All hospital records shall be on the form required by the hospital and shall include a preoperative and postoperative diagnosis and the operation performed together with a description of the procedure performed.

2. *Surgeries*

a. Prior to performing any surgery a written consult from a second ophthalmologist shall be obtained. The consulting ophthalmologists shall be Board certified and approved by the Commission from a list of at least three (3) ophthalmologists submitted to the Commission by the Respondent. All costs for this second opinion shall be borne by the Respondent unless a second opinion is normally covered by the patient's insurance carrier. Respondent shall not operate unless the consulting ophthalmologist agrees that the operation is necessary;

b. In the event that Respondent performs retinal detachment surgery he must be assisted by a retinal specialist (an ophthalmologist who has had one (1) year of fellowship in retinal surgery following his three (3) year residency in general ophthalmology). Any cost involved in having a retinal specialist assist Respondent shall be borne by Respondent; and

c. Consistent with hospital policy and procedure Respondent shall attempt to schedule surgery in continuous blocks of times rather than interspersed between office visits.

3. *Postoperative care*

a. All postoperative cases, including but not limited to cataract surgeries, cataracts with lens implants, retinal detachments, glaucoma surgeries, laser trabeculoplasty, and corneal surgeries shall be seen for a first follow-up visit at least, if not sooner, within one (1) week after the operation is performed. Appropriate physical findings shall be described concerning the status of the operative eye on each patient. Patients should have further follow-up visits as required.

b. Each postoperative patient shall be re-evaluated by the ophthalmological consultant two months after surgeries and a written report by the consultant of the postoperative findings should be made and kept in the patient's office records; and

c. The name, dosage, and frequency of all medications and drops that a postoperative patient is taking and the termination point must be noted in the patient chart.

4. *Patient Load*

a. Until such time as Respondent employs an ophthalmologic assistant Respondent shall limit the number of patients seen to an average of four (4) an hour, scheduling time for Respondent to have lunch and dinner, except for emergencies; and

b. In the event that Respondent employs an ophthalmologic assistant Respondent shall schedule his patient load reasonably.

And be it further ORDERED six (6) months from the effective date of this Order, that being the date the

Commission signs this Order, Respondent's practice shall be reviewed by a Peer Review Committee from Med Chi consisting of ophthalmologists who have not previously reviewed Respondent's practice to determine if Respondent is in compliance with the conditions of this Order. The Committee will make a report to the Commission of its findings. Respondent's practice shall again be reviewed six (6) months from the initial review and then on an annual basis for two (2) years. In the event that the Committee determines that Respondent has not complied with this Order the Committee shall discuss its report with Respondent prior to submitting it to the Commission.

And be it further ORDERED that in the event that the Commission determines, after notice to Respondent and an opportunity to be heard, that Respondent has not complied with the conditions set forth herein it may revoke this Order and impose any disciplinary sanction it deems appropriate.

HILARY T. O'HERLIHY MD, **Chairman**
Commission on Medical Discipline of Maryland

Consent

By this Consent, knowingly and voluntarily executed by me solely for the purpose of settlement and these administrative proceedings without admission of any of the allegations contained in Findings of Fact or in the charge letter of December 27, 1983, or in the Conclusions of Law herein I hereby accept and submit to the foregoing Order, the Findings of Fact and Conclusions of Law and support thereof.

GERALD A. MILLER MD

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Miscellaneous Meetings

May 20–22 Clinical Applications of Stress Testing Techniques in Coronary Heart Disease, American College of Cardiology's Learning Center in Bethesda. Fee: $375, members; $435, nonmembers; 16.5 Cat I credits. Info: ACC Learning Center Registrar, 9111 Old Georgetown Rd., Bethesda, MD 20814 (301-897-5400, ext. 241).

May 22 The Challenge of Hypertension Compliance, How to Increase Patient Adherence, presented by the Center for Health Education, Inc. at North Charles General Hospital, 5 p.m.–7 p.m. (snacks); 2 AMA Cat I credits, 2 prescribed hours AAFP. Info: J. Mannion 301-837-2705.

Jun 4 Seminar in Infectious Diseases, Maryland General Hospital, 827 Linden Ave., Baltimore, 8 a.m.–3 p.m. Registration, $15 (lunch included). 7 Cat I credits. Info: Department of Medicine 301-728-3765.

Jun 5–7 Current Concepts in Oncology and Hematologic Malignancies, Philadelphia. Info: Registrar, American College of Physicians, 4200 Pine St., Philadelphia, PA 19104.

Jun 10–12 Consensus Development Conference on Electroconvulsive Therapy. NIH Clinical Center, Masur Auditorium, 9000 Rockville Pike, Bethesda, MD, Info: M. Dillon, Prospect Associates, Suite 401, 2115 East Jefferson St., Rockville, MD 20852 (301-468-6555).

Jun 13–14 The Principles and Applications of Epidemiology, University of Virginia Medical Center. Fee: $65. Info: J. Jagger, Box 180, University of Virginia Medical Center, Charlottesville, VA 22908 (804-924-5159 or 924-5668).

Jun 13–15 Sixth Annual Institute on Medical Hypnosis, George Washington University Medical Center. Fee: $275 MDs, DDSs, PhDs; $125 allied health students of medicine, dentistry, or psychology; 20 credits. Info: Office of Continuing Education, George Washington University Medical Center, 2300 K Street, NW, Washington, DC 20037 (202-676-4285).

Jun 16–21 Eighth Annual Eastern Shore Medical Symposium, Rehoboth Beach, DE. Sponsored by Jefferson Medical College, The Medical Society of Delaware, University of Delaware. 29 AMA Cat I credits. Info: S. Brocka, University of Delaware, Wilcastle Center, 2800 Pennsylvania Ave., Wilmington, DE 19806 (302-573-4400).

Jul 26–28 Seventh Annual Pediatrics Primary Care Conference: Pediatrics at the Beach, presented by The Childrens Medical Center/General Pediatrics and the Office of Continuing Medical Education at The Medical College of Virginia. Fee: $275 physician's, $225 physicians-in-training and health care physicians; 13 AMA Cat I credits, 13 PREP credits, 1.3 CEUs. Info: B. Winn, Program Coordinator, CME, Box 48, MCV Station, Richmond, VA 23298 (804-786-0494).

Aug 4–9 An Intensive Review of Internal Medicine, Jefferson Medical College in cooperation with the University of Delaware, 45 Cat I AMA credits. Info: S. Brocka, University of Delaware, 2800 Pennsylvania Ave., Wilmington, DE 19806 (302-573-4400).

• • •

Taylor Manor Hospital CME Lectures

All lectures at 3 p.m. in the Psychiatric Center at Taylor Manor Hospital, Ellicott City, MD unless otherwise indicated. Info: Taylor Manor Hospital, College Ave., Ellicott City, MD 21043 (301-465-3322)

Jun 12 Self-Mutilation in the Young
Sep 11 Forensic Psychology Update; Current Critical Issues in Mental Health Law

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The Johns Hopkins Medical Institution

All courses at the Turner Auditorium Building unless otherwise indicated. Sponsored Continued Education Activities for 1984–85. Info: Office of Continuing Education, 720 Rutland Ave., Turner Auditorium, Baltimore, MD 21205 (301-955-5880).

Jun 6–7 Cancer and Nutrition: A 1985 Update on Chemoprevention Trials and Therapeutic Managment. Info: A Kearney (301-955-6046).

Jun 13–14 National Eye Trauma Meeting, sponsored by National Eye Trauma System and The Wilmer Institute, The Johns Hopkins Medical Institutions, to be held at the Washington Hilton, 1919 Connecticut Ave., NW. Fee: $175.

Jun 17–19 Toxicology Update '85. Fee: $450, $250 for Johns Hopkins Health Associates (membership organization); 24 AMA Cat I credits.

Sep 20–21 Rheumatology Update, 1985, sponsored by The Johns Hopkins University School of Medicine, The Maryland Society for Rheumatic Diseases, Maryland Lupus Foundation, and The Arthritis Foundation, Maryland Chapter. Fee: $100 physicians, $50 arthritis health professions, $50 nurses; 1 AMA Cat I credit.

Continuously throughout the year: One-week Microsurgery Training Course, Basic techniques and principles, individualized instruction, and practice sessions. Fee: $1,200; 40 AMA Cat I credits. Info: Prog. Coord. (301-955-3169).

The Department of Radiology and Radiological Science, offers several courses in abdominal and obstetrical ultrasound: courses scheduled Jan 14 to Dec 6, 1985. Info: Joan Mosmiller, Department of Radiology (301-955-8450).

Basic Practicum—June 3–7; Aug 5–9; Sep 23–27. Fee: $460; 40 AMA Cat I credits.

Advanced Practicum—Dec 2–6. Fee $460; 40 AMA Cat I credits.

Visiting Physicians offered weekly throughout the year for experience in the lab and participation in reading sessions. By appointment. Fee: $460; 40 AMA Cat I credits.

Advanced Obstetrics and Gynecology course designed for obstetricians who have been using real time ultrasound. Nov 18–20. Fee: $325; 24 AMA Cat I credits.

Diagnostic Ultrasound in Obstetrics and Gynecology course given annually attracts world's leading experts in the field of obstetrical and gynecology ultrasound. Sep 12–13, 1985; 16 AMA Cat I credits.

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University of Maryland School of Medicine

CME Courses: For each course additional information may be obtained by contacting Program of Continuing Education, University of Maryland School of Medicine, Room 300, MSTF, 10 South Pine St., Baltimore, MD 21201 (301-528-3956).

June 17–18 Symposium on Perinatal Endocrinology. Baltimore. Fee: $150; 14 AMA Cat I credits and 14 ACOG cognates.

June 23–28 Eleventh Annual Family Medicine Review Course, Ocean City. Fee: $350.

June 27–29 Dermatology Days, Ocean City. Early fee: $230; 11.25 AMA Cat I credits.

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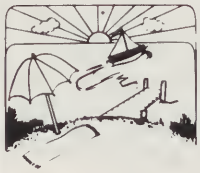
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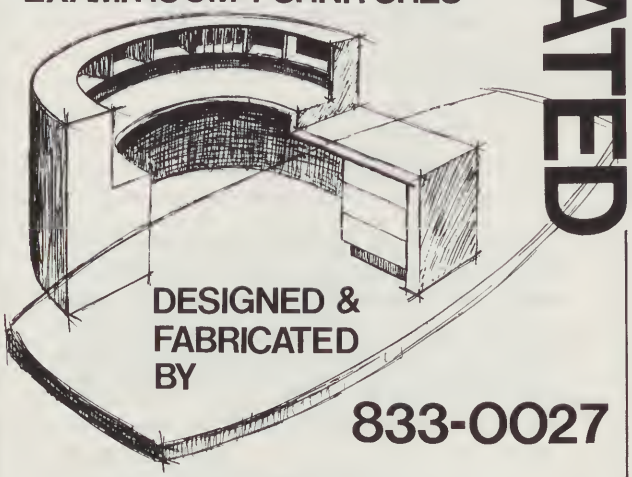
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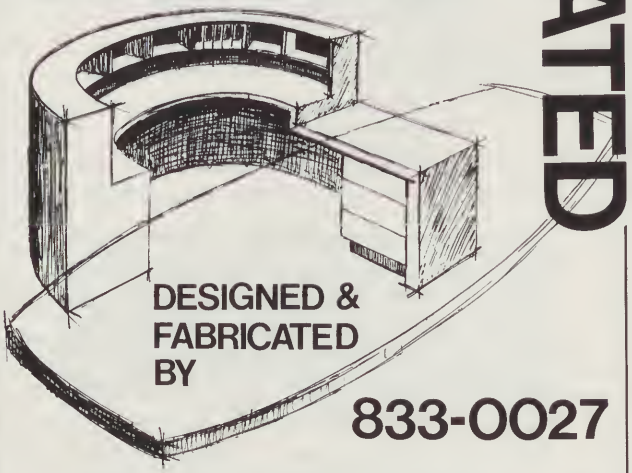
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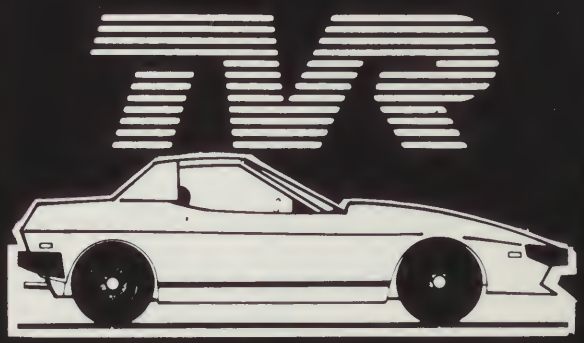
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April Day Studio 458
Arthritis Foundation 512
Associated Speech & Language Services 523
Ayerst Laboratories 450
BTR Realty Inc. 437
Blue Shield of Maryland 418
Bon Secours Professional Center 430
Business Automation, Inc. 513
Campbell Laboratories, Inc. 435
The Carousel Hotel 462
Cellular One 426
Commercial Brokerage Group 458
Computer Terminal Service 423
Crawford Door Sales of Md. 511
Diagnostic Assay Services, Inc. 419
Eli Lilly & Co. 429
Elkridge Estates 523
Emergency Medical Group 521
Family Home Care 511
Family Recovery Center 517
John M.T. Finney III Realtor® 453
GMC Truck Center 511
Gordon & Heneson PA 488
Greater Baltimore Medical Center 520
Gundry Hospital 462
Health Care Expo. '85 427
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Intracare Corp. 476
JBA Leasing 422
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St. Agnes Hospital 520
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Spectrum Emergency Care 520
E. R. Squibb & Sons Inc. 469
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Stuart Pharmaceutical 421
Sunspace Design Studio 522
Tekmatix NA 521
Towson Valley Motors 524
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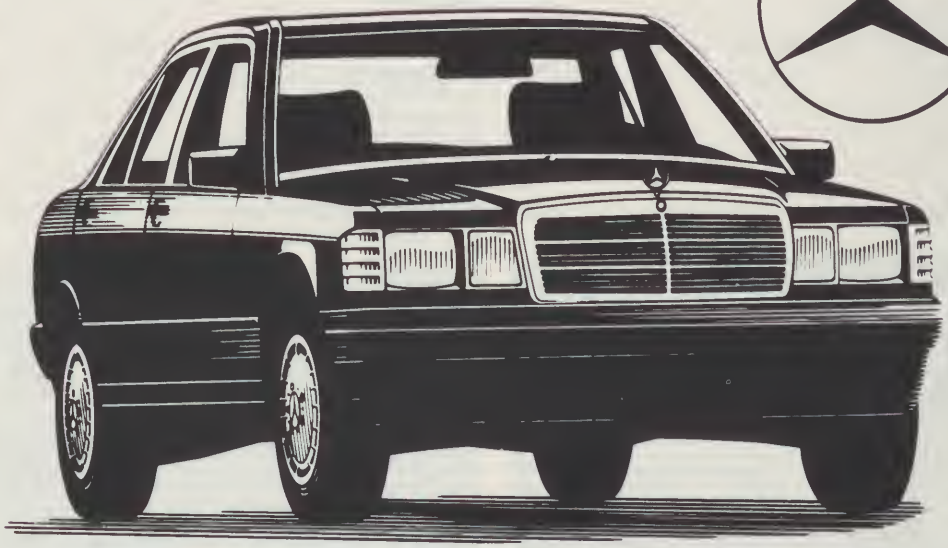
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MISCELLANY

Executive Director's Newsletter 541
Information for Authors 548
Change of Address Form 557
Medicolegal Hotline 569
Medical Miscellany 586, 598
Physician Placement Service 587
Doctors Take Note 614
Classified Ads 617
Hotline Numbers 618
Advertisers' Index 619

ARTICLES

Use of 24-hour pH Monitoring for Gastroesophageal Reflux—Salah M. Nasrallah MD 571

Quantitative Assessment of Burn Wound Progress—Ronald E. Goans MD 576

The Miasmatic and Microscopic Explanations for Disease in the European Past—Vincent J. Knapp PhD 583

Corneal Transplant Donation—Richard M. Susel MD 588

Osteoarthritis IX: Biomechanical Factors, Prevention, and Nonpharmacologic Management—Anneli H. Navarro MEd and Joan D. Sutton MSN 591

Hematuria from Metastatic Cancer to the Kidney: Case Report and Literature Review—May M. Alhashimi MD and Steven H. Krasnow MD 595

DEPARTMENTS

Semiannual Meeting Announcements 546

Commentary—Samuel Morrison MD 551

HBP Commentary 552

Auxiliary 553

Maryland Oncology Newsletter 555

Library Page 556

The Impaired Physician 558

Disease Control Newsletter 563

One Minute with Diabetes 569

Your Medical Faculty at Work 570

Rehabilitation Medicine—The Dysfunctional Pain Patient—Returning to Work: A Preliminary Report—Norman B. Rosen MD, Kenneth Sharoff LCSW, and Vikram Khanna MHS 605

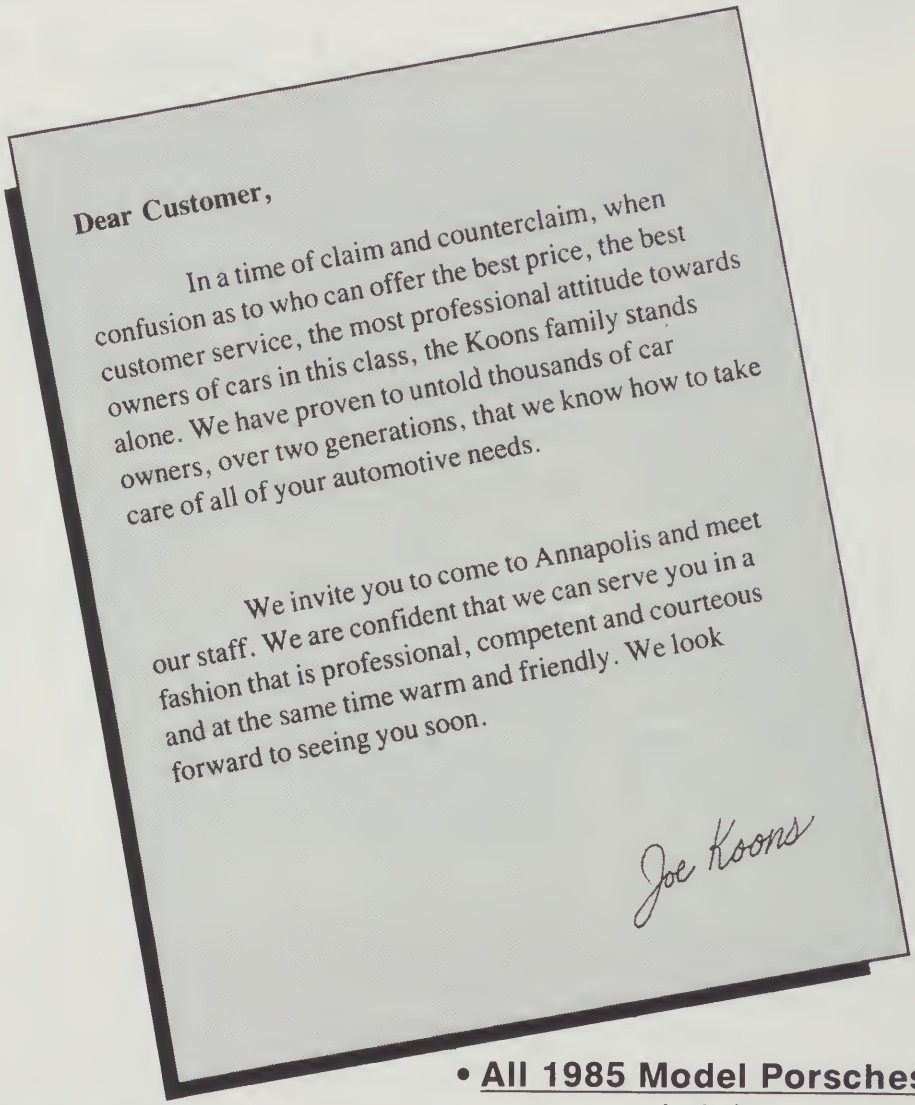
On the cover: Facsimile of a pictorial broadside of 1665–66. From Bell, W. G., *The Great Plague in London in 1665*. London, 1924. See article beginning on page 583, "Miasmatic and Microscopic Explanations . . . ."

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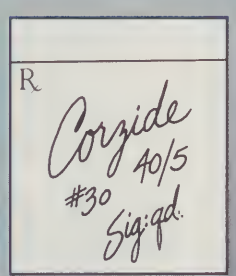
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*Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure: The 1984 report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure. Arch Intern Med 144:1045-1057, 1984.

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CONTRAINDICATIONS: Nadolol — Bronchial asthma, sinus bradycardia and greater than first degree conduction block, cardiogenic shock, and overt cardiac failure (see WARNINGS). **Bendroflumethiazide** — Anuria, and in those with previous hypersensitivity to bendroflumethiazide or other sulfonamide-derived drugs.

WARNINGS: Nadolol — Cardiac Failure — Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta-blockade may precipitate more severe failure. Although beta-blockers should be avoided in overt congestive heart failure, if necessary, they can be used with caution in patients with a history of failure who are well compensated, usually with digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle. IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta-blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, digitalize and/or give diuretics, and closely observe response, or discontinue nadolol (gradually, if possible).

Exacerbation of Ischemic Heart Disease Following Abrupt Withdrawal — Hypersensitivity to catecholamines has been observed in patients withdrawn from beta-blocker therapy; exacerbation of angina and, in some cases, myocardial infarction have occurred after *abrupt* discontinuation of such therapy. When discontinuing chronic use of nadolol, particularly in patients with ischemic heart disease, gradually reduce dosage over a 1- to 2-week period and carefully monitor the patient. Reinstitute nadolol promptly (at least temporarily) and take other measures appropriate for management of unstable angina if angina markedly worsens or acute coronary insufficiency develops. Warn patients not to interrupt or discontinue therapy without physician's advice. Because coronary artery disease is common and may be unrecognized, it may be prudent not to discontinue nadolol therapy abruptly even in patients treated only for hypertension.

Nonallergic Bronchospesm (e.g., chronic bronchitis, emphysema) — PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA-BLOCKERS. Administer nadolol with caution since it may block bronchodilation produced by endogenous or exogenous catecholamine stimulation of $beta_2$ receptors. **Major Surgery** — Because beta blockade impairs the ability of the heart to respond to reflex stimuli and may increase the risks of general anesthesia and surgical procedures, resulting in protracted hypotension or low cardiac output, it has generally been suggested that such therapy should be withdrawn several days prior to surgery. Recognition of the increased sensitivity to catecholamines of patients recently withdrawn from beta-blocker therapy, however, has made this recommendation controversial. If possible, withdraw beta-blockers well before surgery takes place. In emergency surgery, inform the anesthesiologist that the patient is on beta-blocker therapy. Use of beta-receptor agonists such as isoproterenol, dopamine, dobutamine, or levarterenol can reverse the effects of nadolol. Difficulty in restarting and maintaining the heart beat has also been reported with beta-adrenergic receptor blocking agents. **Diabetes and Hypoglycemia** — Beta-adrenergic blockade may prevent the appearance of premonitory signs and symptoms (e.g., tachycardia and blood pressure changes) of acute hypoglycemia. This is especially important with labile diabetics. Beta-blockade also reduces release of insulin in response to hyperglycemia; therefore, it may be necessary to adjust dose of antidiabetic drugs. **Thyrotoxicosis** — Beta-adrenergic blockade may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism. To avoid abrupt withdrawal of beta-adrenergic blockade which might precipitate a thyroid storm, carefully manage patients suspected of developing thyrotoxicosis.

Bendroflumethiazide — Use with caution in severe renal disease. In patients with renal disease, azotemia may be precipitated. With impaired renal function, effects of the drug may be cumulative. Use with caution in impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma. Sensitivity reactions may occur in patients with a history of allergy or bronchial asthma. Possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

PRECAUTIONS: General — Nadolol — Use with caution in patients with impaired hepatic or renal function (see DOSAGE AND ADMINISTRATION).

Bendroflumethiazide — At appropriate intervals, perform serum electrolytes determination to detect possible electrolyte imbalance warning signs of which are dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and G.I. disturbances such as nausea and vomiting. Observe patients for clinical signs of fluid or electrolyte imbalance; namely, hyponatremia, hypochloremic alkalosis, hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Drugs such as digitalis may influence serum electrolytes. Hypokalemia may develop, especially with brisk diuresis, in presence of severe cirrhosis. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Response of the heart to toxic effects of digitalis can be exaggerated with hypokalemia. Use potassium supplements such as high potassium foods to avoid or treat hypokalemia. Any chloride deficit is generally mild and usually does not require specific therapy except under extraordinary circumstances (as in liver or renal disease). Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction rather than salt administration except in rare instances when the hyponatremia is life threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain thiazide-treated patients. Latent diabetes mellitus may become manifest during thiazide therapy. Antihypertensive effects of bendroflumethiazide may be enhanced in the postsympathectomy patient.

Careful reappraisal of therapy and consideration given to withholding or stopping diuretic therapy is necessary if rising nonprotein nitrogen or BUN (indicative of progressive renal impairment) occurs. Thiazides may decrease serum PBI levels without signs of thyroid disturbance. Thiazides decrease calcium excretion. Pathologic changes in parathyroid gland with hypercalcemia and hypophosphatemia have been occasionally observed with prolonged therapy. Common complications of hyperparathyroidism have not been seen.

Information for Patients — Warn patients, especially those with evidence of coronary arter insufficiency, against interruption or discontinuation of nadolol without physician's advic Although cardiac failure rarely occurs in properly selected patients, advise patients bein treated with beta-adrenergic blocking agents to consult physician at the first sign or sympto of impending failure. Advise patients of proper course if dose inadvertently missed.

Laboratory Tests — Regularly monitor serum and urine electrolyte levels (see WARNING *Bendroflumethiazide*, and PRECAUTIONS, *General, Bendroflumethiazide).*

Drug Interactions — Nadolol — When administered concurrently the following drugs ma interact with beta-adrenergic blocking agents: **Anesthetics, general** — exaggeration anesthetic-induced hypotension (see WARNINGS, *Nadolol, Major Surgery).* **Antidiabetic drugs (oral agents and insulin)** — hypoglycemia or hyperglycemia; adjust antidiabetic dru dosage accordingly (see WARNINGS, *Nadolol, Diabetes and Hypoglycemia).* **Catechol emine-depleting drugs (e.g., reserpine)** — additive effect; monitor closely for evidence o hypotension and/or excessive bradycardia.

Bendroflumethiazide — When administered concurrently the following drugs may interac with thiazide diuretics: **Alcohol, barbiturates, or narcotics** — may potentiate orthostati hypotension. **Antidiabetic drugs (oral agents and insulin)** — thiazide-induced hyperglyc cemia may require adjustment of antidiabetic drug dosage. **Other antihypertensiv drugs** — additive or potentiated effect. **Corticosteroids, ACTH** — intensified electrolyte d pletion, particularly hypokalemia. **Ganglionic or peripheral adrenergic blocking drugs** potentiated effect. **Preanesthetic and anesthetic agents** — effects may be potentiate adjust dosage accordingly. **Pressor amines (e.g., norepinephrine)** — possible decreas response but not sufficient to preclude their use. **Skeletal muscle relaxants, nondepolar izing (e.g., tubocurarine)** — possible increased response.

Drug/Laboratory Test Interactions — Discontinue thiazides before tests for parathyroi function (see PRECAUTIONS, *General, Bendroflumethiazide).*

Carcinogenesis, Mutagenesis, Impairment of Fertility — Nadolol — In 1 to 2 years ora toxicologic studies in mice, rats, and dogs, nadolol did not produce significant toxic effects. I 2-year oral carcinogenic studies in rats and mice, nadolol did not produce neoplastic, prene plastic, or nonneoplastic pathologic lesions. **Bendroflumethiazide** — Long-term studies i animals have not been performed.

Pregnancy — Teratogenic Effects — Nadolol — Category C. In animal reproductio studies with nadolol, evidence of embryo- and fetotoxicity was found in rabbits, but not in rat or hamsters, at doses 5 to 10 times greater (on a mg/kg basis) than the maximum indicate human dose; no teratogenic potential was seen in any of these species. There are no well-con trolled studies in pregnant women; therefore, use nadolol in pregnant women only if potentia benefit justifies potential risk to the fetus. **Bendroflumethiazide** — Category C. Anima reproduction studies have not been conducted. This drug's effect on the fetus when adminis tered to a pregnant woman or its effect on reproductive capacity is not known. Bendroflu methiazide should be given to a pregnant woman only if clearly needed. **Nonteretogenic Effects** — Since thiazides cross the placental barrier and appear in cord blood, weigh antici pated benefit of the drug in pregnant women against possible hazards to the fetus; these hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other reaction which have occurred in adults.

Nursing Mothers — Both nadolol and bendroflumethiazide are excreted in human milk Because of the potential for serious adverse reactions in nursing infants either discontinue nursing or discontinue therapy, taking into account the importance of CORZIDE (Nadolo Bendroflumethiazide Tablets) to the mother.

Pediatric Use — Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Nadolol — Most adverse effects have been mild and transient an have rarely required nadolol withdrawal. **Cardiovascular** — Bradycardia with heart rates o less than 60 beats per minute occurs commonly, and heart rates below 40 beats per minut and/or symptomatic bradycardia were seen in about 2 of 100 patients. Symptoms o peripheral vascular insufficiency, usually of the Raynaud type, have occurred in approx mately 2 of 100 patients. Cardiac failure, hypotension, and rhythm/conduction disturbance have each occurred in about 1 of 100 patients. Single instances of first degree and third degree heart block have been reported; intensification of AV block is a known effect of beta blockers (see also CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS). **Central Ner vous System** — Dizziness or fatigue reported in approximately 2 of 100 patients; pares thesias, sedation, and change in behavior reported in approximately 6 of 1000 patients **Respiratory** — Bronchospasm reported in approximately 1 of 1000 patients (see CONTRAINDICATIONS and WARNINGS). **Gastrointestinal** — Nausea, diarrhea, abdomina discomfort, constipation, vomiting, indigestion, anorexia, bloating, and flatulence each reported in 1 to 5 of 1000 patients. **Miscellaneous** — Each of the following reported in 1 to 5 of 1000 patients: rash; pruritus; headache; dry mouth, eyes, or skin; impotence or decreased libido; facial swelling; weight gain; slurred speech; cough; nasal stuffiness; sweating; tinnitus; blurred vision. Although relationship to drug usage is not clear, sleep disturbances have been reported. The oculomucocutaneous syndrome associated with practolol has not been reported with nadolol. The following adverse reactions may also occur: **Central Nervous System** — reversible mental depression progressing to catatonia; visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss; emotional lability with slightly clouded sensorium, decreased performance on neuropsychometrics. **Gastrointestinal** — mesenteric arterial thrombosis; ischemic colitis. **Hematologic** — agranulocytosis; thrombocytopenic or nonthrombocytopenic purpura. **Allergic** — fever combined with aching and sore throat; laryngospasm; respiratory distress. **Miscellaneous** — reversible alopecia; Peyronie's disease; erythematous rash; arterial insufficiency.

Bendroflumethiazide — Gastrointestinal System — anorexia, gastric irritation, nausea, vomiting, cramping, diarrhea, constipation, jaundice (intrahepatic cholestatic jaundice), pancreatitis. **Central Nervous System** — dizziness, vertigo, paresthesia, headache, xanthopsia. **Hematologic** — leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia. **Dermatologic-Hypersensitivity** — purpura, photosensitivity, rash, urticaria, necrotizing angiitis (vasculitis, cutaneous vasculitis). **Cardiovascular** — orthostatic hypotension may occur. **Other** — hyperglycemia, glycosuria, occasional metabolic acidosis in diabetics; hyperuricemia, allergic glomerulonephritis, muscle spasm, weakness, restlessness. Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy withdrawn.

OVERDOSAGE: Nadolol may cause excessive bradycardia, cardiac failure, hypotension, or bronchospasm if overdosed. Overdosage of thiazides may cause lethargy, which may progress to coma within a few hours, with minimal depression of respiration and cardiovascular function and without evidence of serum electrolyte changes or dehydration. Gastrointestinal irritation and hypermotility may occur. Transitory increase in BUN and serum electrolyte changes may occur, especially in patients with renal impairment.

Treatment — Nadolol can be removed from the general circulation by hemodialysis. In determining duration of corrective therapy, take note of the long duration of the effect of nadolol. In addition to gastric lavage, employ the following measures, as appropriate. **Excessive Bradycardia** — Administer atropine (0.25 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously. **Cardiac Failure** — Administer a digitalis glycoside and diuretic. It has been reported that glucagon may also be useful in this situation. **Hypotension** — Administer vasopressors, e.g., epinephrine or levarterenol. (There is evidence that epinephrine may be the drug of choice.) **Bronchospasm** — Administer a $beta_2$ stimulating agent and/or a theophylline derivative. **Stupor or Coma** — Supportive therapy as warranted. **Gastrointestinal Effects** — Symptomatic treatment as needed. **BUN and/or Serum Electrolyte Abnormalities** — Institute supportive measures as required to maintain hydration, electrolyte balance, respiration, and cardiovascular and renal function.

DOSAGE AND ADMINISTRATION: DOSAGE MUST BE INDIVIDUALIZED. Patients with renal failure require adjustment in dosing interval; see package insert for dosage in these patients.

Consult package insert before prescribing CORZIDE (Nadolol-Bendroflumethiazide Tablets).

HOW SUPPLIED: Available as scored tablets containing 40 mg nadolol combined with 5 mg bendroflumethiazide and 80 mg nadolol combined with 5 mg bendroflumethiazide in bottles of 100.

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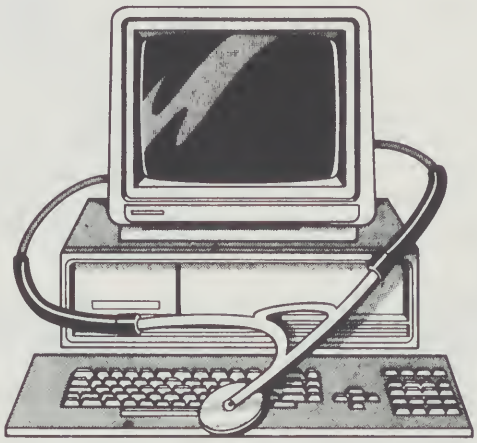
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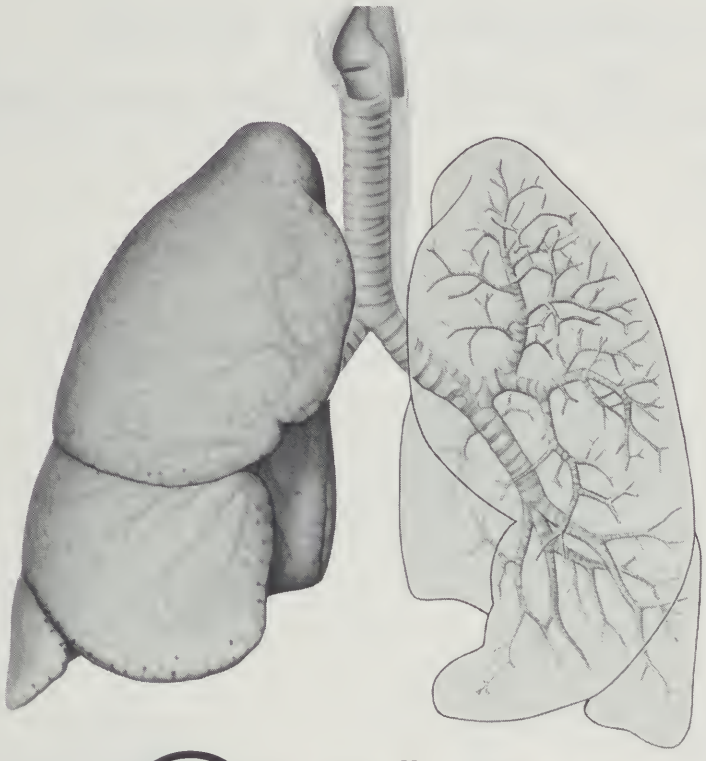
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Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Precautions: *General Precautions* — If an allergic reaction to Ceclor* (cefaclor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest* tablets but not with Tes-Tape* (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy — *Pregnancy Category B* — Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor* (cefaclor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers — Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/mℓ at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Ceclor is administered to a nursing woman.

Usage in Children — Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below.

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbiliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic — Slight elevations in SGDT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic — Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal — Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[D617B2R]

Note: Ceclor* (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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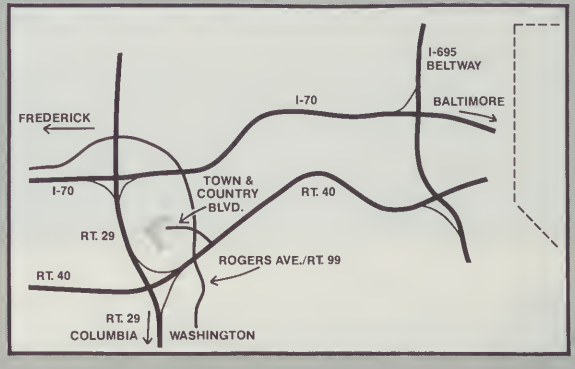


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Executive Director's Newsletter

June 1985

PERSONAL ID NUMBER

Effective June 1, all physicians with hospital privileges must have a common identification number for use at hospitals where their privileges are maintained. The Maryland Hospital Association is requesting that all hospitals submit a list of privileged physicians to the Faculty for assignment of such a number.

THIS NUMBER IS CONFIDENTIAL and cannot be released to any group except the hospital's utilization review committee, the Faculty, the Commission on Medical Discipline, and the Board of Medical Examiners.

Identification of a physician from this number can only be made by (1) the Faculty, (2) the physician, and (3) the hospitals where the physician holds privileges. Physicians are urged not to reveal their special ID number to any other person.

1985 PPA CENSUS

All physicians in the U.S. have now received a Physicians' Professional Activities Census form. Completion of the form assures accurate classification in official AMA records and in the 30th edition of the American Medical Directory. These records also serve as the basis for the distribution of educational information.

The PPA Census is conducted by the AMA periodically for the purpose of identifying the self-designated practice specialties and current professional activities of every physician in the country. All physicians--AMA members and nonmembers--are listed in the Directory, as well as those who are no longer in active practice.

Failure to complete the Census form may result in inaccurate classification in AMA records and in the 30th edition of the American Medical Directory.

SEMIANNUAL MEETING RESOLUTIONS

Resolutions to be considered by the House of Delegates at its Semiannual Session on Saturday, September 28, 1985 must be received in the Faculty office by

FRIDAY, AUGUST 2, 1985

Resolutions must be sponsored by a member or component society of the Faculty, the Council, or committees of the Faculty. A resolution introduced by an individual member must have the endorsement of either one-third of the membership of his component society or 30 members of his component society, whichever is smaller.

LICENSURE FOR MAJOR MEDICAL EQUIPMENT

Physicians who own and operate major medical equipment costing over $600,000 (exclusive of housing, site) are required as of June 1 to have a license for such equipment.

Application for provisional licenses must be in the hands of the Department of Health and Mental Hygiene by July 1, 1985. For further information, contact Judith Wood at the Faculty office, 301-539-0872 or 800-492-1056.

ORGAN PROCUREMENT INFO

This month marks the end of a national public awareness campaign called SECOND CHANCE, sponsored locally by WJZ-TV, Channel 13, aimed at alerting the public to the critical shortages of organ donors and organ transplants. Its ongoing effectiveness depends on the extent to which each and every physician in Maryland becomes involved with the issue. Your awareness of the procedures for organ procurement and your willingness and cooperation in facilitating them is critical. Without that knowledge and involvement, giving life a second chance is little more than an unrealized dream, rather than the flourishing, humane reality it can be. For additional information, call the Maryland Organ Procurement Center in Baltimore at 301-528-3626.

PRO COMPLICATIONS

The Faculty's Council urges all members to notify the Faculty office of any patient complications that arise from the implementation of the new PRO regulations. These notices will be referred to the Faculty's Committee on Utilization and Quality Control Peer Review, which is charged with reviewing the Maryland Foundation For Health Care activities in this regard.

Details, including patient's name and pertinent information, should be in writing.

PARKING PROBLEMS

Effective immediately, the Faculty parking lot will be unavailable for members (except on an extremely limited basis) because of construction on School 49. Parking arrangements have been made with the BSO parking garage located on the northeast corner of Preston and Cathedral Streets. Physicians attending meetings in the Faculty Building may have their parking ticket validated at the Faculty office when using this parking facility. PLEASE NOTE THIS FACILITY CLOSES AT 7:00 P.M.

We hope this inconvenience will be over by the end of the year.

John Sargent
Executive Director

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Deposits and monies are refundable (Less a $25 administrative fee as NOTED UNDER PARAGRAPH 7 IN THE TOUR PARTICIPANTS CONTRACT). CANCELLATION MUST BE RECEIVED AT MED-CHI BY JUNE 24, 1985. AFTER THIS DATE, REFUNDS WILL ONLY BY GIVEN IF THE RESERVATION IS RESOLD.

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Information for Authors

Med-Chi members reading papers before organizations are invited to submit their papers to the MMJ for consideration for publication.

The *Maryland Medical Journal* is the monthly publication of the Medical and Chirurgical Faculty of the State of Maryland. Its goals are educational and informative: the publishing of scientific articles and other technical information as well as editorials, special articles (evaluations, position papers, reviews of nonscientific subjects), membership news, notices of medical events, legislative and governmental news, meetings, continuing education courses, and programs and policies of the Faculty.

Manuscripts may be sent to Editor *MMJ*, 1211 Cathedral St., Baltimore, MD 21201. Articles are accepted for publication on the condition that they are contributed solely to this journal. Transmittal letters should designate one author as correspondent and include his/her address and telephone number. Manuscripts are reviewed by the editor, editorial board members, and guest reviewers. The final decision is reserved for the Editor.

Specifications

Manuscripts must be original typed copy, double-spaced throughout (including text, case reports, legends, tables, and references) with margins of at least one inch. Number pages consecutively. Please submit two additional copies.

Include in the manuscript the concise title, full name of the author (or authors) with highest degree, academic and professional titles, affiliations, and any institutional or other credits.

An introductory synopsis/abstract of approximately 100–150 words is required.

Tables are to be typed on separate sheets of paper, numbered, and have a brief descriptive title. The Editor reserves the right to edit tables. Be sure that statistics are consistent in both tables and text.

References are limited to those citations noted in the text. References are to be typed double-spaced and numbered consecutively as they appear in text. They will be examined critically at the time of review and must be kept to a minimum. Personal communciations and unpublished data should not be included. The following are necessary: names of all authors, complete title of article cited (lower case), name of journal abbreviated according to *Index Medicus*, volume number, first and last page numbers, and year of publication. For more extensive information about preparing medical articles for publication, the editors suggest the International Committee of Medical Journal Editors: Uniform requirements for manuscripts submitted to biomedical journals. The complete document is available in the June 1982 issue of the *Annals of Internal Medicine*.

Illustrations are material that cannot be set in type. Photographic material must be submitted as high-contrast, glossy prints. Drawings and graphs must be done professionally in india ink on high-grade white drawing paper. *Omit illustrations that do not increase understanding of text, and limit them to a reasonable number.* Four or fewer illustrations should be adequate for a manuscript of 4 to 5 typed pages. Legends are to be typed on a separate sheet of paper. Type on a gummed label and affix to the back of each illustration: figure number, title of manuscript, name of senior author, and arrow indicating top. Legends for illustrations should be typed on a separate page with numbers corresponding to those on the photographs and drawings. *Cost of printing color photographs must be borne by the author.*

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Manuscripts are subject to editorial modification and such revisions necessary to being them into conformity with *Journal* style.

Galley proofs will be mailed to the principal author and, if not returned by the specified date, will be considered approved as typeset.

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*JAMA, Volume 248, No. 3, pages 336-339
Yearbook of Medicine, 1983, pages 66-67

Commentary

Changing Patterns

Medicine is big business. Organizatons are taking over hospitals, initiating their own, and openly indicating they are in the medical business for profit. It is clear hospitals must diversify into comprehensive health care. Perhaps physicians have not recognized the trend.

There has been considerable discussion that emphasis should be on "voluntary practice modification rather than intensive governmental intervention." This recently was expressed by James E. Davis MD, AMA House Speaker. Yet many physicians are reluctant to initiate practice modification.

Utilization Review points primarily to cost containment. Cost containment places constraints on the quality of care. To contain costs, the physician sometimes appears forced to gamble with his patient's health. The safety factor in quality of care becomes an issue; the physician should not be faced repeatedly with "risk management" or "malpractice."

Those in Utilization Review have been able to do their jobs and may at times make decisions that seem to conflict with PRO guidelines. However, a reviewer can be pleased and surprised to see little criticism or re-review following decisions that experience and knowledge dictate. There is, therefore, a safety zone that is reasonable and acceptable.

On the broader scheme, the direction of medicine should not discourage us too much. Remarkable research is being done. Continuing medical education shows no evidence it will reach its pinnacle; our knowledge at a given time is becoming obsolete at an amazing rate.

Hospitals must and will have the fortitude and resources to adjust to changes. It is our hope that the future of cost containment will be rebudgeted to take into account the basic necessity of quality care. Attacks on the medical guild will not change this basic truism: There is only one quality of care: the very best we can render.

However, rationing of medical care has been applied in some countries. Rationing of health care because of economic constraints already has begun in this country. If you're poor or elderly, your care is being rationed now. The vital question is: Who will make these judgments?

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HBP Commentary

Second Edition: *Management of Essential Hypertension*—A Review

DONALD O. FEDDER DrPH and R. PATTERSON RUSSELL MD

F. Gilbert McMahon MD did his residency in internal medicine at the University of Wisconsin, where he also studied endocrinology. He is Director of the Clinical Research Center in New Orleans and since 1968 has been affiliated with the Tulane University Medical School, where he is Clinical Professor of Medicine. In 1978 Dr. McMahon published a medical text, *Management of Essential Hypertension*, which sold over 56,000 copies. Last year, a second edition was published with an added subtitle, *The New Low-Dose Era*, reflecting important changes in the management of hypertension over the last few years. We comment on the usefulness of this report.

McMahon's second edition on the treatment of hypertension is a major contribution to the field and is important to both the academic and the community physician.[1] The author examines the treatment of high blood pressure (HBP) in light of the recent publication of major clinical trial results and the controversies raised by these studies and makes recommendations based on his analysis and conclusions. These recommendations differ from the consensus document published by the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure (JNC III), previously reviewed in this column.[2,3] McMahon takes a clinician's view, and while his recommendations are clear, he cannot be accused of oversimplification of the controversies. Thus, it is important for readers to assess the differences between the JNC III recommendations and those of McMahon in the management of their hypertensive patients.

Although the basic organization is similar to the first edition, there are important changes and additions. In reviewing the new thinking regarding drug therapy and the stepped-care approach, McMahon lays a few old dogmas to rest. For instance:

Old Dogma	New Thinking
Treat all patients with mild hypertension with drugs.	Nondrug therapy is safe, effective, and inexpensive.
Always start treatment with a thiazide.	Step 1 may be a thiazide, beta-blocker, or other agent, depending on the individual.
Always give full doses of thiazides.	Low-dose therapy is effective and minimizes possible biochemical abnormalities.

The first chapter, "Synopsis," is an excellent overview of the subject, providing the reader with what may be called an executive summary of the test. Here the author details the problem of HBP and its dimensions and discusses the "definition controversy." One point needs comment. The author concludes that most U.S. authorities define adult hypertension as pressure that exceeds 140 mm Hg systolic and/or 90 mm Hg diastolic. However, most clinicians, epidemiologists and the American Heart Association now define hypertension in the adult as arterial pressure *equal to* or greater than 140/90 mm Hg. McMahon's working classification of the severity of hypertension also differs from that put forth in the JNC III report in that he defines moderate as a diastolic blood pressure of 105–119 mm Hg and severe as greater than 120 mm Hg, whereas JNC III defines moderate 105–114 mm Hg and severe as equal to or greater than 115 mm Hg.

At another point in the chapter McMahon speaks of the natural course of the disease and defines mild hypertension as a diastolic pressure of 90–99 mm Hg. These differences in terminology may be confusing to the community physician seeking uniform guidelines. The author then discusses relevant risk factors and provides a further analysis of epidemiologic studies relating blood pressures to the risk of premature morbidity and mortality. Attention is given to the controversy as to how to treat mild hypertension in the absence of target organ damage, with the author clearly defining **nondrug** therapy as **treatment**, which is consistent with the JNC III recommendations.

Comments concerning the need for hospitalization of patients with malignant hypertension are tempered with a note of caution about lowering blood pressure too rapidly. However, the advice to sedate the patient and evaluate carefully before initiating treatment is outmoded and not in the patient's best interest. The first chapter concludes with a list of therapeutic principles that are valuable (but not referenced) and are sometimes equivocal (for example, "consider home blood pressure determination" or "teach the patient about . . . medications and possible side effects").

Chapter Two is devoted to nondrug treatment of hypertension. McMahon reviews a number of studies that have shown that a moderate reduction of salt intake can lead to a decrease in blood pressure of 10/5 mm Hg and that, for the overweight patient, each kg of weight loss appears to lower blood pressure about 2.5/1.5 mm Hg. He recommends nondrug therapy indefinitely for persons with DBP 90–94 mm Hg and with no

HBP Commentary is contributed by the Maryland High Blood Pressure Commission, 201 W. Preston St., Baltimore, MD 21201 (301-383-7263). Editors: R. Patterson Russell MD, Past Chairman; Donald O. Fedder PharmBS, DrPH, Chairman; and Carol Lewis MPH, ScD, Executive Director.

risk factors present. In this type of recommendation the difference between McMahon and JNC III is most apparent. The consensus document recommendation is to "individualize" therapy. McMahon, free of the need to develop consensus, is able to make a clear, across-the-board recommendation. In addition, exercise, relaxation, and biofeedback are given a good treatment in the context of what definitive data exist as well as the limits of that data.

Subsequent chapters deal with various drugs; since publication was in 1984, most of the newer agents are included. Drugs are characterized by class and compared and contrasted, as appropriate. These chapters are well-organized and authoritative, and presented so the reader can search out information on a single agent, a class of drug, or review the entire collection of hypertensive agents.

The second edition of *Management of Essential Hypertension* serves as a ready reference for treatment of either the routine or the problem patient and should be a welcome addition to the libraries of all who have a significant number of patients with HBP. One area, however, could use amplification. Long-term maintenance of blood pressure control recently has been identified by the National High Blood Pressure Coordinating Council as the major current problem in achieving further reduction of hypertensive morbidity and mortality. But concepts of health education are given only sketchy attention in this test, as is the need for the patient to change behavior if control is to be achieved and maintained. Since there are considerable lapses of time between a patient's visits to his/her physician, time during which the patient is on his/her own to commit or omit appropriate and prescribed behaviors, the physician might appreciate guidance in patient education techniques.

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3. September 1984.

Auxiliary

The Second Annual Mid-Atlantic Conference was held in Shepherdstown, West Virginia in March.* Sponsored by the state auxiliaries of Virginia, West Virginia, and Maryland the conference topic was Prenatal and Postnatal Problems. Three guest panelists spoke on the effects of smoking, alcohol, and other drugs on the mother and child. Douglas D. Glover MD, Associate Professor, Obstetrics and Gynecology, Marshall University School of Medicine in Huntington, West Virginia addressed the effects of smoking. Shaukat A. Ashai MD, Chief of Obstetrics and Gynecology, Columbia Medical Plan in Columbia, Maryland covered problems with alcohol and FAS (Fetal Alcohol Syndrome). Keith Edwards MD, Obstetrician and Gynecologist in private practice in Bluefield, West Virginia discussed the use of drugs during pregnancy. A film on FAS was shown and a question-and-answer session followed.

Wednesday evening's session dealt with the rising concern about the increasing prevalence of adolescent pregnancy—children having children. Albert Strauss, Jr., MD, a pediatrician in private practice in Hagerstown, Maryland presented his views as a pediatrician in Western rural Maryland. The speakers were well received, and the approximately 55 attending auxilians returned home with useful information.

The Thursday session was "Idea Sharing" among the states with a special skit on pre-natal care presented by Mary Strauss, Vice President of Eastern Region for the American Medical Association Auxiliary, and Velman Seif, Past-President of Virginia's Auxiliary. Discussion on the introduction of educational programs into the public school systems followed. Maryland gave information on approaching the school superintendent with the film on FAS and on his enthusiastic approval of plans to incorporate it in the Middle School program. (A second film on Juvenile Diabetes, which will be introduced to the schools next, was previewed by the group and was followed by questions and answers of a Maryland auxilian, whose daughter was diagnosed with juvenile diabetes five years ago).

The primary focus was to heighten awareness of the importance of prenatal months and to increase understanding of postnatal problems.

* Information supplied by Mildred Taylor.

Auxiliary to the Medical and Chirurgical Faculty of the State of Maryland. Mrs. Kathleen S. Karpers, President.

Another Man's Poison

If you accept that each person is unique—even if that person has a drinking or drug problem—then it's easy to see why a treatment program must be individualized. One man's successful treatment is another man's failure.

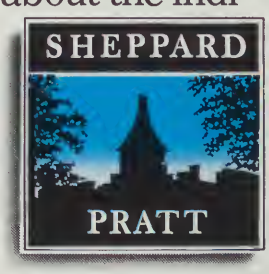
At Sheppard Pratt, we don't shoehorn people into a program, sacrificing individualization. Instead we adapt the program to the individual.

There are givens, of course. We're abstinence-oriented, and work according to the principles of Alcoholics Anonymous and Narcotics Anonymous. We provide a warm, home-like environment. We start with a thorough evaluation of the patient, the problem and its effects. Then, using a multidisciplinary team of professionals, we move each patient through individual and group counseling designed to get results as quickly as possible, including outpatient follow-through.

For some, this means intense confrontation. For others, gentle guidance. Our sensitivity, experience and flexibility enable us to determine the best approach.

If you are sometimes in a position to refer alcoholics or drug abusers to suitable treatment centers, learn more about the individualized approach at Sheppard Pratt.

To get general information about the Sheppard Pratt Substance Abuse Program, or to discuss an individual case, contact: Dr. David Waltos, Admissions Officer, Sheppard and Enoch Pratt Hospital, P.O. Box 6815, Baltimore, Maryland 21204. (301) 823-8200.



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Maryland Oncology Newsletter

Prognosis and Management of Cutaneous Melanoma

The behavior of melanoma is unpredictable. However, certain prognostic factors play a major role in the management and outcome of this disease.

The depth of invasion according to Breslow carries a major prognostic factor, regardless of Clark's levels. Melanoma of 0.76 mm or less in thickness has a 100 percent survival rate with no recurrence after local excision with a 1 cm margin. The deeper and more invasive the melanoma, the higher the incidence of recurrence and metastases after surgery. Patients with lesions over 0.76 mm but less than 1.5 mm have a 60 to 80 percent 15-year survival, while those with melanoma of over 1.5 mm level of invasion have only a 25 percent 5-year survival rate. Similarly, ulcerated melanoma also carries a very guarded prognosis. Such lesions are treated by wide excision of the skin, subcutaneous tissues, and underlying fascia and skin grafting.

However, the questions remains: How wide should the wide excision be? Different reports recommend 3 to 5 cm margin, while 2 cm margin is allowed for melanoma in the skin of the face. Currently, there is no scientific evidence for such claims, except for some retrospective studies that point to high local recurrence rates after small excisions. Therefore, a national prospective controlled study is now comparing 2 cm versus 4 cm excisional margins.

Regional Lymph Nodes

The most important prognostic factor in patients with melanoma is the status of the regional lymph nodes. Patients presenting with regional lymph node metastases (Stage II disease) have poor prognosis. The prognosis worsens with the increase of number of involved lymph nodes. On the other hand, survival of patients with uninvolved, that is, negative, regional lymph nodes depends on the depth of the invasion at the primary site as stated above.

While all surgeons agree to perform *therapeutic* lymph node dissection for regional lymph node metastases, controversy exists on the role of *elective* (also known as *prophylactic*) regional lymphadenectomy in patients with no clinical evidence of lymph node metastases. Several retrospective studies created a controversy ; while some of us believed that elective lymphadenectomy did not improve the survival, others claimed that it did as 15 to 20 percent of early metastases to the regional lymph nodes are undetected clinically. Two prospective studies, one from the World Health Organization[1] and the other from Mayo Clinic,[2] have shown that prophylactic lymphadenectomy played no major role in prolongation of survival. However, Balch *et al.*[3] in a retrospective review pointed out that patients with melanoma of less than 1 mm in thickness (who have good prognosis) and those with over 4 mm (who have very poor prognosis) do not benefit from elective lymphadenectomy.

Therefore, a national study was initiated over a year ago to study the role of elective lymphadenectomy in patients who have melanoma of 1 to 4 mm thickness.

Adjuvant Therapy

This is the administration of other therapeutic modalities, within four weeks of "curative surgery," in hope of preventing or delaying recurrences and of prolonging survival. Such therapy is given in a controlled, randomized fashion in patients with guarded prognosis, those with deep invasion at the primary site or regional lymph node metastases.

Adjuvant chemotherapy by imidazole carboxamide (DTIC) and adjuvant nonspecific immunotherapy by BCG failed to show any benefit.[4] Therefore, we initiated two programs for patients at high risk after their curative surgery. Those with Stage I melanoma of head and neck areas, trunk, or proximal extremities such as shoulders or buttocks, or with Stage II disease will be offered immunotherapy using melanoma cell vaccine. Patients with melanoma of distal extremities are offered hyperthermic limb perfusion with chemotherapy.

Local Recurrences

These can be treated by wide local excision, but a second recurrence is possible. Therefore, we have added hyperthermic limb perfusion for lesions on the extremities. For local recurrence on the trunk or head and neck, BCG is injected intralesionally. More recently we have been using PPD (250Tu) intralesionally, after a single injection of BCG, thus reducing the incidence of skin ulceration. Although early results using BCG and PPD are encouraging for local control, this approach has not prevented the development of systemic metastases after 1 to 1.5 years.

Widespread Metastases

These patients are candidates for palliative chemotherapy. The most effective agent is a imidazole carboxamide (DTIC) with a response rate of 20 percent of three months' duration. Because of such disappointing results, patients presenting with small lesions amenable

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If you have questions, please write or call the Surgical Oncology Program at the University of Maryland Medical System, Room N13E02, Baltimore, MD 21201 (301-528-5224).

to surgical exterpation are resected. Patients with extensive metastases are candidates for systemic chemotherapy. A combination of BCNU + Melphelan + Oncovin is being tried at the University of Maryland Cancer Center. Brain metastases are common in melanoma and are treated with radiation therapy with poor outcome.

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E. GEORGE ELIAS MD
University of Maryland, Surgical Oncology Program

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The Library Page

Computerized Literature Searches

Each month in 1985 an increasing number of physicians will add a computer to their practices. Although no current survey is available to pinpoint the number of physicians who have computers, published surveys do show the rapid acceptance of the computer.

The affordable microcomputer was first introduced in 1977. A 1981 survey conducted by the American Medical Association estimated that 19 percent of physicians were using computers in their practice. Surveys conducted in 1982 by the American Society of Internal Medicine and in 1983 by the American Academy of Family Physicians reported similar estimates for their membership. Another 1982 survey conducted by *Medical Economics* reported the same 20 percent figure and that 40 percent of their respondents indicated they were considering adding a computer to their practices over the next two years.

As competition and technology lower costs, computers become more attractive. It is safe to say that the computer is fast becoming a way of life for the medical profession. This attractiveness is further enhanced by the versatility. While aspects of practice management such as accounts payable and receivable and general ledger are primary considerations for physicians who are buying computers, clinical applications, for example, electronic recording of patient's histories, have become low-cost add ons.

End-user literature searching is another inexpensive add on for the physician computer user. End-user searching has the physician conducting his/her own computerized search. The library and the librarian as an intermediary step in this process are bypassed. The benefits to the physician are many. Turnaround time is improved since a search can be conducted at a terminal whenever a physician wants. Time of day is no longer a factor. Medical information is available twenty-four hours a day. A physician can conduct a search at his/her convenience in the evening after office hours when libraries are closed. Physicians can manipulate the search material themselves. They can keep adding requirements until they get the information they want.

Two factors allow physicians to do their own searching. Costs are now within acceptable limits to physicians. For example, the cost for adding the necessary telecommunication software and hardware to a computer system are low. In many cases they are already in place when a system is purchased. Competition among data base vendors for physician users has caused connect time charges and monthly minimum charges to decline. Another factor is improved technology. In-

Medical and Chirurgical Faculty of the State of Maryland Library, 1211 Cathedral Street, Baltimore, MD 21201. Joseph E. Jensen, Librarian.

creased transmission speeds mean less connect time to transfer information and therefore lower costs.

Data base suppliers and advanced technology are making information easier to gather. The process is not as confusing as it appeared a few years ago. For example, to search for articles about dropping malpractice coverage, "going bare," a physician would look for the words *going* and *bare* to be adjacent to one another in the title, the abstract, and the text. The addition of full-text searching of major medical textbooks and information files allows physicians access to the latest information. This is especially useful regarding drug interactions.

Vendors

Although there are many data base vendors of interest to physicians in the computer marketplace, four are very heavily used. These are the National Library of Medicine, the Bibliographic Retrieval System (BRS), Dialog, Inc., and the American Medical Association/GTE network. The National Library of Medicine produces the MEDLARS files that index journal articles, books, audiovisuals, as well as files related to cancer literature and to bioethics among its different data bases. The MEDLARS file also can be accessed through both BRS and Dialog. Vendors offer other files for use that provide related literature. BRS through its Colleague file allows access to textbook searching. The AMA/GTE file includes articles related to the socioeconomic aspects of medicine and separate files dealing with drug interactions and with diagnostic information. Although many vendors offer services that overlap one another, physicians can select the services best suited to their needs.

The Library, which in end-user searching is bypassed, now has a new role. Libraries are becoming educators to physicians interested in end-user searching. For example, the Faculty Library will soon be conducting workshops to improve searching techniques. This will lower a physician's cost. Libraries will become the common ground to objectively explain available systems to physicians and to simplify the process of accessing particular systems.

The Faculty Library will be playing this role in the future to help physician members do their own searching. If you are interested, please contact the Faculty's library staff for assistance.

ADAM SZCZEPANIAK
Associate Librarian

Selected Medical Literature Searches

The following are among the computerized medical literature searches provided to Med-Chi members during March 1985.

		Number of Citations
1	Adverse effects of imipramine in children	12
2	Amiodarone and pulmonary fibrosis	13
3	Computers and physician's professional practice	19
4	Etiology of hyperemesis gravidarum	14
5	Health services accessibility and the elderly woman	24
6	Informed consent and Maryland	8
7	Kidney calculi and lithotripsy	23
8	Nuclear magnetic resonance and behavioral or mental disorders	25
9	Sex preselection	14
10	Treatment and prognosis of synovioma	21

If you would like a copy of one of these searches or a search run on any biomedical topic, call or write the library.

SUSAN E. HARMAN
Reference and Circulation Librarian

Doctor, Planning to Relocate?

If you are moving or planning to, please let us know so that you won't miss a single issue of the **Journal.** Just fill out the form below and mail it to: Doris Cicchini, **Journal,** 1211 Cathedral St., Balto., MD 21201.

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Address: .....
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Telephone: .....
IMPORTANT: Date Effective: .....
Signature: ..... Date: .....

The Impaired Physician

What He Doesn't Know Will Hurt Him

There Must Be Something the Matter with Him

There must be something the matter with him because he would not be acting as he does unless there was.
Therefore he is acting the way he is because there is something the matter with him.
He does not think there is anything the matter with him because one of the things that is the matter with him is that he does not think there is anything the matter with him.
Therefore we have to help him realize that the fact that he does not think there is anything the matter with him is one of the things that is the matter with him.

R.D. Laing

• • •

One of the most puzzling aspects of the challenging and fascinating illness alcoholism is the intensity of one of its major symptoms: denial. This is especially true in the case of physicians who are alcoholics. We watch in growing horror as a treasured colleague gradually consumes himself, his family, and finally his career. As the process accelerates, it is increasingly recognizable by others but seemingly invisible to the self being consumed. We watch, whispering to each other, "Why can't he see what's happening? Why doesn't he stop drinking?"

The not always so obvious answer is that he *cannot see* what is happening to him. If he can partly, he is fully capable of reciting a detailed list of excellent reasons why it is the fault of others. If not the fault of others, what is happening appears to you more serious than it really is. Knowing the details of the situation as only he does (and will be happy to disclose to you in great detail), it can be understood that although things superficially may look bad, they are not nearly as bad as they seem, and anyway . . .

Blaming, rationalizing, minimizing, and denying. These are the finely honed mental mechanisms our colleagues use, with skill and conviction, to separate us from our concern and to protect themselves from what they fear most: an inability to obtain their drug of choice, or a suitable substitute, on which they have become dependent.

If we are not knowledgeable and insightful or if we also are experiencing denial regarding our own use of mood-altering drugs, we will accept the rationalizations, join in the blaming, or finally agree matters are not really as bad as they seem. This is a common reaction and enables our colleague to persist in his delusion.

Eventually the delusion is not simply that alcohol or other drug taking *has no role* in causing his problems, but that it is a secondary, minimal, probably unrelated, or at best, consequential rather than causative phenomena that will improve or disappear once the *real problem* is resolved (for example, nagging wife, too rigid medical staff or hospital rules, a child's illness, an excessive work load, too demanding patients, an unsympathetic policeman, judge, or IRS agent).

The delusional conviction does not result from many years of drinking or drugging but is the cause of them. "How can I possibly live without drinking?" is the constant, plaintive cry of the confronted alcoholic. Social drinkers not intensively knowledgeable of the infinite complexity of the delusional system constructed by the chemically dependent can hardly appreciate how strongly it is used in defense of the continued need for drug use to sustain normal life. No drug-dependent person believes a comfortable life is remotely possible without drugs. Strength of conviction is the origin of the delusional system.

In the drinking/drugging history of a chemically dependent physician, such denial does not simply spring into existence at one magical point in order to keep him from avoiding the awful truth. Rather, it is an initial and constant companion as his illness gradually unfolds and manifests itself. Denial is present at the beginning, middle, and end. It is like meningococcus that is discoverable at the beginning and sometimes at the end of a full spectrum of other signs and symptoms, at some point affording a correct diagnosis of meningoccemia with meningococcidal meningitis.

If you think alcohol or other mood-altering drugs have a role in the many adversities occurring in the life of a valued colleague, you are probably right. The chemically dependent physician *can* realize what is happening to him, but only with your help.

The Committee on Physician Rehabilitation can provide expert help for this special need. Express your concern to be of help. Call 539-0872 or the Hot Line 727-0120.

MARTIN J. VALASKE MD
Member, Committee on Physician Rehabilitation

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Before prescribing, see complete prescribing information in SK&F CO. literature or *PDR*. The following is a brief summary.

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This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: **Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired.** If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K^+ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K^+ intake. **Associated widened QRS complex or arrhythmia requires prompt additional therapy.** Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: The bioavailability of the hydrochlorothiazide component of 'Dyazide' is about 50% of the bioavailability of the single entity. Theoretically, a patient transferred from the single entities of Dyrenium (triamterene, SK&F CO.) and hydrochlorothiazide may show an increase in blood pressure or fluid retention. Similarly, it is also possible that the lesser hydrochlorothiazide bioavailability could lead to increased serum potassium levels. However, extensive clinical experience with 'Dyazide' suggests that these conditions have not been commonly observed in clinical practice. Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function.

Thiazides may add to or potentiate the action of other antihypertensive drugs.

Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth; anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions; nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances; postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

Supplied: **'Dyazide' is supplied as a red and white capsule, in bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); in Patient-Pak™ unit-of-use bottles of 100.**

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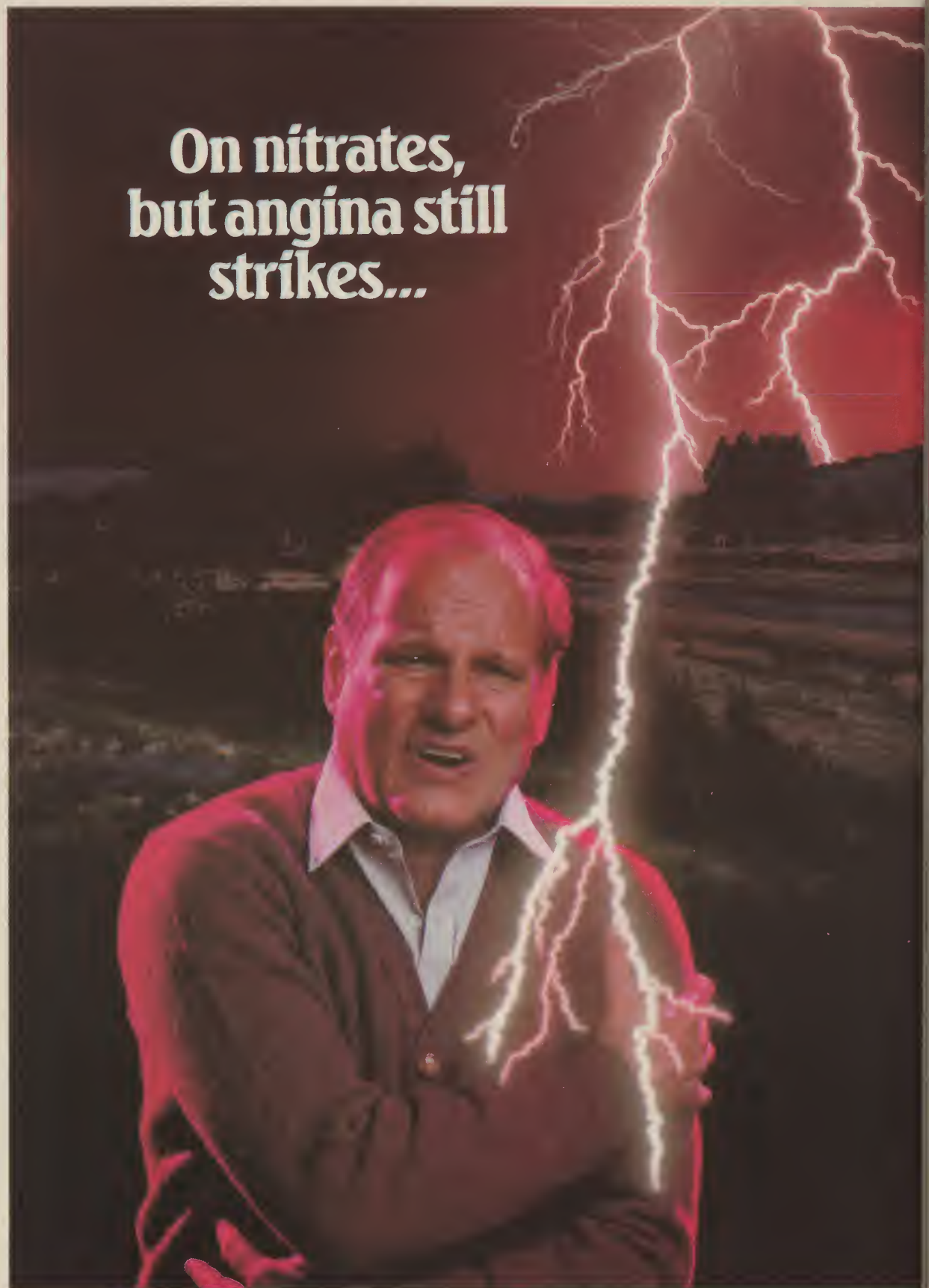


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Cardiovascular contraindications to the use of Isoptin are similar to those of beta blockers: severe left ventricular dysfunction, hypotension (systolic pressure <90 mm Hg) or cardiogenic shock, sick sinus syndrome (if no artificial pacemaker is present) and second- or third-degree AV block.

So, the next time a nitrate is not enough, add Isoptin... for more comprehensive antianginal protection without side effects which may cramp an active life style.



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Please see brief summary on following page.

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80 mg and 120 mg scored, film-coated tablets

Contraindications: Severe left ventricular dysfunction (see *Warnings),* hypotension (systolic pressure < 90 mm Hg) or cardiogenic shock, sick sinus syndrome (except in patients with a functioning artificial ventricular pacemaker), 2nd- or 3rd-degree AV block. **Warnings:** ISOPTIN should be avoided in patients with severe left ventricular dysfunction (e.g., ejection fraction < 30% or moderate to severe symptoms of cardiac failure) and in patients with any degree of ventricular dysfunction if they are receiving a beta blocker. (See *Precautions.)* Patients with milder ventricular dysfunction should, if possible, be controlled with optimum doses of digitalis and/or diuretics before ISOPTIN is used. (Note interactions with digoxin under *Precautions.*) ISOPTIN may occasionally produce hypotension (usually asymptomatic, orthostatic, mild and controlled by decrease in ISOPTIN dose). Elevations of transaminases with and without concomitant elevations in alkaline phosphatase and bilirubin have been reported. Such elevations may disappear even with continued treatment; however, four cases of hepatocellular injury by verapamil have been proven by rechallenge. Periodic monitoring of liver function is prudent during verapamil therapy. Patients with atrial flutter or fibrillation and an accessory AV pathway (e.g. W-P-W or L-G-L syndromes) may develop increased antegrade conduction across the aberrant pathway bypassing the AV node, producing a very rapid ventricular response after receiving ISOPTIN (or digitalis). Treatment is usually D.C.-cardioversion, which has been used safely and effectively after ISOPTIN. Because of verapamil's effect on AV conduction and the SA node, 1° AV block and transient bradycardia may occur. High grade block, however, has been infrequently observed. Marked 1° or progressive 2° or 3° AV block requires a dosage reduction or, rarely, discontinuation and institution of appropriate therapy depending upon the clinical situation. Patients with hypertrophic cardiomyopathy (IHSS) received verapamil in doses up to 720 mg/day. It must be appreciated that this group of patients had a serious disease with a high mortality rate and that most were refractory or intolerant to propranolol. A variety of serious adverse effects were seen in this group of patients including sinus bradycardia, 2° AV block, sinus arrest, pulmonary edema and/or severe hypotension. Most adverse effects responded well to dose reduction and only rarely was verapamil discontinued. **Precautions:** ISOPTIN should be given cautiously to patients with impaired hepatic function (in severe dysfunction use about 30% of the normal dose) or impaired renal function, and patients should be monitored for abnormal prolongation of the PR interval or other signs of excessive pharmacologic effects. Studies in a small number of patients suggest that concomitant use of ISOPTIN and beta blockers may be beneficial in patients with chronic stable angina. Combined therapy can also have adverse effects on cardiac function. Therefore, until further studies are completed, ISOPTIN should be used alone, if possible. If combined therapy is used, close surveillance of vital signs and clinical status should be carried out. Combined therapy with ISOPTIN and propranolol should usually be avoided in patients with AV conduction abnormalities and/or depressed left ventricular function. Chronic ISOPTIN treatment increases serum digoxin levels by 50% to 70% during the first week of therapy, which can result in digitalis toxicity. The digoxin dose should be reduced when ISOPTIN is given, and the patients should be carefully monitored to avoid over- or under-digitalization. ISOPTIN may have an additive effect on lowering blood pressure in patients receiving oral antihypertensive agents. Disopyramide should not be given within 48 hours before or 24 hours after ISOPTIN administration. Until further data are obtained, combined ISOPTIN and quinidine therapy in patients with hypertrophic cardiomyopathy should probably be avoided, since significant hypotension may result. Clinical experience with the concomitant use of ISOPTIN and short- and long-acting nitrates suggest beneficial interaction without undesirable drug interactions. Adequate animal carcinogenicity studies have not been performed. One study in rats did not suggest a tumorigenic potential, and verapamil was not mutagenic in the Ames test. *Pregnancy Category C*: There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy, labor and delivery only if clearly needed. It is not known whether verapamil is excreted in breast milk; therefore, nursing should be discontinued during ISOPTIN use. **Adverse Reactions:** Hypotension (2.9%), peripheral edema (1.7%), AV block: 3rd degree (0.8%), bradycardia: HR < 50/min (1.1%), CHF or pulmonary edema (0.9%), dizziness (3.6%), headache (1.8%), fatigue (1.1%), constipation (6.3%), nausea (1.6%), elevations of liver enzymes have been reported. (See *Warnings.*) The following reactions, reported in less than 0.5%, occurred under circumstances where a causal relationship is not certain: ecchymosis, bruising, gynecomastia, psychotic symptoms, confusion, paresthesia, insomnia, somnolence, equilibrium disorder, blurred vision, syncope, muscle cramp, shakiness, claudication, hair loss, macules, spotty menstruation. **How Supplied:** ISOPTIN (verapamil HCl) is supplied in round, scored, film-coated tablets containing either 80 mg or 120 mg of verapamil hydrochloride and embossed with "ISOPTIN 80" or "ISOPTIN 120" on one side and with "KNOLL" on the reverse side. Revised August, 1984. 2385

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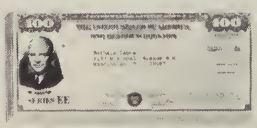


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MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE

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JUNE 1985

MEDICAL WORKUP OF INDIVIDUALS WITH POSITIVE HTLV-III ANTIBODY TESTS

The ELISA test for the antibody to the HTLV-III virus responsible for AIDS, will become widely available by the beginning of June. The test, developed initially for use by blood collection centers to screen potential donors for the HTLV-III antibody, will be used in all blood and plasma centers. The concern that members of high risk groups might offer to donate blood in order to find out their antibody status has prompted the Centers for Disease Control, and the State of Maryland to establish Alternate Test Sites in each county health department and in Baltimore City, where these individuals can go to get tested. At many of these sites, patients may be tested without giving their name. These alternate test sites will notify those individuals who are found to be seropositive in person, provide some counseling and interpretation, and refer both symptomatic and asymptomatic individuals for further medical evaluation.

The Alternate Test Sites employ a second ELISA and an additional corroborating test, the Western Blot, before advising a patient of his positive status. When evaluating an individual who has been notified of his seropositivity, it is important to first establish whether or not his status has been confirmed by these additional tests. For those individuals who have had only a single ELISA, a repeat specimen should be obtained for testing. Several private laboratories and the State Laboratory offer Western Blot testing.

Medical workup of seropositive individuals is directed towards identifying any symptoms that may be associated with AIDS or the AIDS related complex. These findings (constitutional symptoms, unexplained lymphadenopathy, anergy, thrombocytopenia, evidence of opportunistic infections) have been extensively described elsewhere. A careful, directed history, physical examination, and complete blood count and platelet count should identify those individuals who require some intensive investigation. Detailed recommendations are to be found in the Department of Health and Mental Hygiene (DHMH), Office of Disease Control and Epidemiology Newsletter published in the February 1985 Maryland Medical Journal. Since HTLV-III is a sexually-transmitted disease, it is also appropriate to test for other STD's including syphilis and gonorrhea.

Positive findings identified as a result of this initial workup will require further investigation. Depending on the specific finding, this workup might include T-cell subset quantitation for helper and suppressor cell number, further skin testing for anergy, specific anti-platelet antibody studies, biopsy of suspicious lesions or referral for consultation, depending on the health provider's familiarity with HTLV-III related disease manifestations. A model questionnaire is outlined in the attachment.

Providers may also wish to consult the publication "Acquired Immune Deficiency Syndrome: Information for Maryland Physicians, Dentists and Other Health Care Providers", available from the Maryland Department of Health and Mental Hygiene, for more specific information regarding workup of symptomatic individuals. A statewide toll free hotline has been established to provide telephone information and referral for concerned laymen and professionals, in Baltimore, 947-AIDS; elsewhere in Maryland, 1-800-638-6252.

Submitted by: Bernard M. Branson, M.D., Medical Director, Health Education Resource Organization, and Baltimore City Health Department.

MINIMUM INITIAL EVALUATION OF HTLV-III REACTORS

1. Identifying information

2. HTLV-III information
   a. Was testing for HTLV-III performed at an Alernate Test Site?
   b. If not, which laboratory performed the HTLV-III test(s)? When?, by which method was the testing performed: ELISA, Western Blot, or both?

3. Medical History
   a. Risk factor history. Is the person:
      (1) A male who has had sex with another male since 1978?
      (2) An intravenous drug user, sharing needles with others?
      (3) A hemophiliac.
      (4) A sexual partner of a person in one of the above risk groups?
      (5) A sexual partner of a prostitute?
      (6) A recipient of blood or blood products since 1978? If so, when and where?
      (7) An immigrant from Haiti since 1978?
      (8) A contact of a person known to have AIDS? If so, what was the nature of the contact?
   b. History of the present illness and review of systems, including:
      (1) Unintentional weight loss of at least 10 pounds in the past 3 months.
      (2) Fever of at least 2 weeks duration.
      (3) Night sweats.
      (4) Malaise (weakness or fatigue).
      (5) Skin rashes, painful blisters on the skin, or other skin lesions and discolorations.
      (6) Swollen glands for at least 2 weeks duration.
      (7) White patches in the mouth.
      (8) Shortness of breath for at least 2 weeks.
      (9) Cough for at least 2 weeks.
      (10) Diarrhea for at least 2 weeks.

c. Past medical history, including:

(1) History of hepatitis, amebiasis, giardiasis, gonorrhea, syphilis, venereal warts, genital herpes simplex, including pertinent treatment history.
(2) History of a positive tuberculin skin test or tuberculosis, including pertinent treatment history.
(3) History of medical condition(s) which may cause immuno-deficiency syndrome.
(4) History of diseases associated with AIDS: Pneumocystis carinii pneumonia, CMV infection, toxoplasmosis, cryptococcosis, disseminated mycobacterial infection, meningitis, candidiasis, disseminated or chronic herpes infection, Kaposi's sarcoma.
(5) Receipt of immunosuppressive or cytotoxic therapy in the past.
(6) Gynecologic history including pregnancy history and birth control method.
(7) Allergies.
(8) Current medications.
(9) Social history, marital status, household composition.
(10) History of blood donations.

4. Physical examination
(1) Vital signs, including weight.
(2) General appearance.
(3) Skin (Kaposi's sarcoma, needle marks).
(4) HEENT (retinal exudates, oral white plaques, herpetic lesions).
(5) Lymphatics (determine the number of palpable nodes at each site, and the size of the largest node at each site).
(6) Chest.
(7) Heart.
(8) Abdomen (size and palpability of liver and spleen).
(9) Genital (discharge, herpetic lesions, warts, hemorrhoids, lice).
(10) Neurologic (cranial nerves, motor, sensory (including vibration, and position); gait, mental status).

5. Laboratory studies
(1) Complete blood count.
(2) White blood cell differential count.
(3) Platelet count.
(4) Syphilis serology.
(5) Repeat HTLV-III test if initial result was based solely on a single ELISA test.

(NOTE: HTLV-III testing is available to practicing physicians in Maryland through the Department of Health and Mental Hygiene, FREE OF CHARGE).

6. Counseling of patient
(1) Health assessment.
(2) Prognosis.
(3) Recommendations for reducing risk of transmission.

7. Referral, if needed, for workup of medical or psychological problems that have been identified.

8. Reschedule persons without signs or symptoms for followup in 6 months.

9. Report all confirmed AIDS cases to the local Health Department. Cases of AIDS-related complex and lymphadenopathy syndrome are reportable in Baltimore City only.

Source: Baltimore City Health Department

HTLV-III ANTIBODY REFERRAL

Alternate test sites for HTLV-III antibody testing have been established in Maryland. A list of medical providers interested in receiving referrals of symptomatic persons or asymptomatic persons who have a positive test for HTLV-IIII antibodies on both ELISA and Western Blot testing is being assembled. Initial evaluation of asymptomatic persons would include a directed history and physical examination, a STS, a CBC, with differential and a platelet count. A more detailed discussion of this medical evaluation is at the beginning of this report as well as the Med-Chi Journal 2/85. Physicians interested in being added to this list should contact the administrator of their local hospital or Dr. Diane Matuszak, Division of Community Epidemiology, DHMH, at 301-383-2644 (225-6698 after June 7, 1985). The list will be comprised of an alphabetical listing of providers, location, telephone number, cost of basic evaluation, payment plans and comments and/or special instructions.

POLICY UPDATED ON MAXIMUM TETANUS DOSES REQUIRED FOR SCHOOL

The Centers for Disease Control (CDC) in consultation with the Immunization Practices Advisory Committee (ACIP), recommends that no more than six doses of tetanus toxoid should be administered prior to the seventh birthday in order to avoid the possibility of tetanus hyperimmunization. In conformance with this recommendation, the Department of Health and Mental Hygiene, in consultation with the Med-Chi, has established six doses of DTP/DT/Td as the maximum that shall be required for any school pupil.

Under this policy, children who received a fifth dose of DTP/DT before the recommended age of 4 to 6 years will be required to receive an additional dose of appropriate vaccine. However, a child who has written evidence of receiving six doses of DTP/DT prior to the fourth birthday shall not be required to have more to attend school. Once ten years have elapsed since the last dose, a Td booster will be medically indicated but will not be required.

NEW TELEPHONE NUMBERS FOR OFFICE OF DISEASE CONTROL & EPIDEMIOLOGY

General Information - 225-6681	TB & Respiratory Disease - 225-6699
STD Disease Control - 225-6688	Animal Bites & Rabies - 225-6711
Immunization Services-225-6677	AIDS Hotline 1 - 800-638-6252

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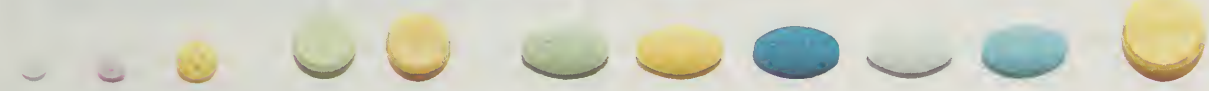


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See following page for brief summary of prescribing information.

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Please consult full prescribing information before use. A summary follows:

INDICATIONS AND USAGE: SORBITRATE (isosorbide dinitrate) is indicated for the treatment and prevention of angina pectoris. All dosage forms of isosorbide dinitrate may be used prophylactically to decrease frequency and severity of anginal attacks and can be expected to decrease the need for sublingual nitroglycerin.

The sublingual and chewable forms of the drug are indicated for acute prophylaxis of angina pectoris when taken a few minutes before situations likely to provoke anginal attacks. Because of a slower onset of effect, the oral forms of isosorbide dinitrate are not indicated for acute prophylaxis.

CONTRAINDICATIONS: SORBITRATE is contraindicated in patients who have shown purported hypersensitivity or idiosyncrasy to it or other nitrates or nitrites. Epinephrine and related compounds are ineffective in reversing the severe hypotensive events associated with overdose and are contraindicated in this situation.

WARNINGS: The benefits of SORBITRATE during the early days of an acute myocardial infarction have not been established. If one elects to use organic nitrates in early infarction, hemodynamic monitoring and frequent clinical assessment should be used because of the potential deleterious effects of hypotension.

PRECAUTIONS: General: Severe hypotensive response, particularly with upright posture, may occur with even small doses of SORBITRATE. The drug should therefore be used with caution in subjects who may have blood volume depletion from diuretic therapy or in subjects who have low systolic blood pressure (eg, below 90 mmHg). Paradoxical bradycardia and increased angina pectoris may accompany nitrate-induced hypotension. Nitrate therapy may aggravate the angina caused by hypertrophic cardiomyopathy.

Marked symptomatic, orthostatic hypotension has been reported when calcium channel blockers and organic nitrates were used in combination. Dose adjustment of either class of agents may be necessary.

Tolerance to this drug and cross-tolerance to other nitrates and nitrites may occur. Tolerance to the vascular and antianginal effects of isosorbide dinitrate or nitroglycerin has been demonstrated in clinical trials, experience through occupational exposure, and in isolated tissue experiments in the laboratory. The importance of tolerance to the appropriate use of isosorbide dinitrate in the management of patients with angina pectoris has not been determined. However, one clinical trial using treadmill exercise tolerance (as an end point) found an 8-hour duration of action of oral isosorbide dinitrate following the first dose (after a 2-week placebo washout) and only a 2-hour duration of effect of the same dose after 1 week of repetitive dosing at conventional dosing intervals. On the other hand, several trials have been able to differentiate isosorbide dinitrate from placebo after 4 weeks of therapy and, in open trials, an effect seems detectable for as long as several months.

Tolerance clearly occurs in industrial workers continuously exposed to nitroglycerin. Moreover, physical dependence also occurs since chest pain, acute myocardial infarction, and even sudden death have occurred during temporary withdrawal of nitroglycerin from the workers. In clinical trials in angina patients, there are reports of anginal attacks being more easily provoked and of rebound in the hemodynamic effects soon after nitrate withdrawal. The relative importance of these observations to the routine, clinical use of isosorbide dinitrate is not known. However, it seems prudent to gradually withdraw patients from isosorbide dinitrate when the therapy is being terminated, rather than stopping the drug abruptly.

Information for Patients: Headache may occur during initial therapy with SORBITRATE. Headache is usually relieved by the use of standard headache remedies or by lowering the dose and tends to disappear after the first week or two of use.

Drug Interactions: Alcohol may enhance any marked sensitivity to the hypotensive effect of nitrates.

Isosorbide dinitrate acts directly on vascular smooth muscle; therefore, any other agent that depends on vascular smooth muscle as the final common path can be expected to have decreased or increased effect depending on the agent.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term studies in animals have been performed to evaluate the carcinogenic potential of this drug. A modified two-litter reproduction study in rats fed isosorbide dinitrate at 25 or 100 mg/kg/day did not reveal any effects on fertility or gestation or any remarkable gross pathology in any parent or offspring fed isosorbide dinitrate as compared with rats fed a basal-controlled diet.

Pregnancy Category C: Isosorbide dinitrate has been shown to cause a dose-related increase in embryotoxicity (increase in mummified pups) in rabbits at oral doses 35 and 150 times the maximum recommended human daily dose. There are no adequate and well-controlled studies in pregnant women. SORBITRATE should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when SORBITRATE is administered to a nursing woman.

Pediatric Use: The safety and effectiveness of SORBITRATE in children has not been established.

ADVERSE REACTIONS: Adverse reactions, particularly headache and hypotension, are dose-related. In clinical trials at various doses, the following have been observed:

Headache is the most common (reported incidence varies widely, apparently being dose-related, with an average occurrence of about 25%) adverse reaction and may be severe and persistent. Cutaneous vasodilation with flushing may occur. Transient episodes of dizziness and weakness, as well as other signs of cerebral ischemia associated with postural hypotension, may occasionally develop (the incidence of reported symptomatic hypotension ranges from 2% to 36%). An occasional individual will exhibit marked sensitivity to the hypotensive effects of nitrates and severe responses (nausea, vomiting, weakness, restlessness, pallor, perspiration, and collapse) may occur even with the usual therapeutic dose. Drug rash and/or exfoliative dermatitis may occasionally occur. Nausea and vomiting appear to be uncommon. Case reports of clinically significant methemoglobinemia are rare at conventional doses of organic nitrates. The formation of methemoglobin is dose-related and, in the case of genetic abnormalities of hemoglobin that favor methemoglobin formation, even conventional doses of organic nitrate could produce harmful concentrations of methemoglobin.

DOSAGE AND ADMINISTRATION: For the treatment of angina pectoris, the usual starting dose for sublingual SORBITRATE is 2.5 to 5 mg; for chewable tablets, 5 mg; for oral (swallowed) tablets, 5 to 20 mg; and for controlled-release forms, 40 mg.

SORBITRATE should be titrated upward until angina is relieved or side effects limit the dose. In ambulatory patients, the magnitude of the incremental dose increase should be guided by measurements of standing blood pressure.

The initial dosage of sublingual or chewable SORBITRATE for prophylactic therapy in angina pectoris patients is generally 5 or 10 mg every 2 to 3 hours. Adequate controlled clinical studies demonstrating the effectiveness of chronic maintenance therapy with these dosage forms have not been reported.

SORBITRATE in oral doses of 10 to 40 mg given every 6 hours or in oral controlled-release doses of 40 to 80 mg given every 8 to 12 hours is generally recommended. The extent to which development of tolerance should modify the dosage program has not been defined. *The oral controlled-release forms of isosorbide dinitrate should not be chewed.*

DOSAGE FORMS AVAILABLE: Sublingual Tablets (2.5, 5, 10 mg); Chewable Tablets (5, 10 mg); Oral Tablets (5, 10, 20, 30, 40 mg); Sustained Action Tablets (40 mg).

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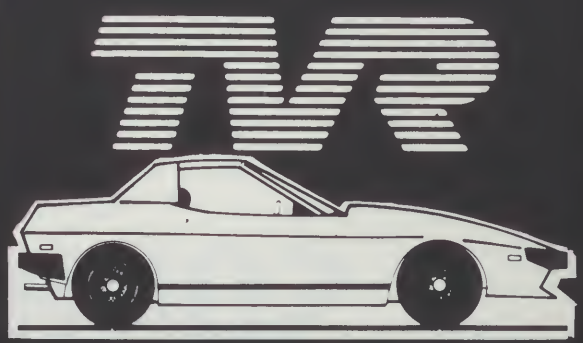
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One Minute with Diabetes

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Labeling of foodstuffs has become more informative as to contents in recent years. Read the label to determine the sweetening agent and calories per serving in all foods.

It is common for "dietetic" and "diabetic" foods (both terms are misnomers) to be advertised as containing "no sugar." The usual sweetening agent is sorbitol, which is not sugar but is very high in calories. Sorbitol cannot be consumed by the diabetic patient in good control without including the calories in the meal plan.

Sweet 'N Low, saccharin, and aspartame may be used in beverages and foodstuffs as a sweetener. These substances are totally safe to use, even during pregnancy, as far as is known at this time.

In selecting fruits and vegetables, one should shop for fresh, frozen unsweetened, or canned water-packed products.

Remember "diet" soft drinks are expensive and do not contribute to ones' health as much as an equivalent amount of water. The following table is a useful guide for sweetening agents.

DeWITT E. DeLAWTER MD

Sweetener	Relative Sweetness (compared to sugar)	Calories for Sweetness (per teaspoon sugar)	Disadvantages	Diabetic Use
Sorbitol	½	36	High calories, may be laxative	Limited for good control
Fructose	1½	12	Some calories	Limited for good control
Sweet 'N Low*	4	4	Some calories	Almost unlimited
Saccharin	300	0	Bitter after taste	Unlimited
Aspartame Equal* Nutrasweet*	200	0	Breaks up at high temperature	Unlimited

* Brand name

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	Vincent O'Donnell MD	*301-530-1830*
July	*Peggy R. Odick, Esq.*	*301-762-5511*
	Eugene H. Owens MD	*301-675-2104*
August	*Jeannette Plante, Esq.*	*301-752-1630*
	David R. Padrino, MD	*301-838-1024*

Your Medical Faculty at Work

The Council and House of Delegates met in session during the Faculty's Annual Meeting at Hunt Valley, MD, and took various positions on Faculty policy.

The House adopted a substitute resolution on PRO activity:

Resolved, That the Medical and Chirurgical Faculty of Maryland strongly recommends to the Maryland Foundation for Health Care that it restudy criteria established in the Professional Review Organization contract, in association with the specialty societies of Maryland, within the next 90 days and revise any and all criteria found to have a potentially adverse effect on the quality of medical care rendered patients in Maryland.

In another substitute resolution, the Faculty's Public Relations Committee was

instructed to develop and direct an effort toward improving and maintaining positive relationships between individual patients and their physicians and to coordinate the activities of local medical societies in this endeavor.

Various bylaw amendments were adopted, one to change the charge and composition of the Hospital Medical Staffs committee; another to include the Deans of Medical Schools in Maryland in Council membership.

The House, on recommendation of the Council, adopted the following resolution:

Resolved, That the current $5 assessment of the active membership be increased to $10 per year, effective January 1, 1986, and expiring December 31, 1988;

Resolved, That funds raised from this additional assessment shall be used for the purpose of hiring a part-time Coordinator to supplement the activities of the Committee on Physician Rehabilitation and act as an additional resource for that Committee; and be it further

Resolved, That existing accumulated funds for use of the Committee on Physician Rehabilitation be used to fund this part-time Coordinator through January 1, 1986 with details such as employment terms to be worked out by the Committee together with the Treasurer.

The House of Delegates, again on recommendation of Council, adopted a resolution dealing with the fee freeze enacted at the 1984 session of the House of Delegates. This reads as follows:

Resolved, That the physicians of Maryland be commended for their response to the 1984 House of Delegates' action urging them to freeze their fees for one year;

Resolved, That members of the Medical and Chirurgical Faculty of the State of Maryland continue their pledge to ensure the highest quality of medical care to all Maryland citizens at a cost that is reasonable and appropriate while always remaining vigilant to every opportunity for containment of health care costs, as well as for instances where courtesy and charity can be given in a dignified and appropriate manner; and

Resolved, That Maryland physicians be urged to continue giving special consideration when setting fees for the unemployed, the uninsured, and those on Medicare and, when warranted, to accept reduced fees, or none at all.

J. D. Drinkard MD, a Towson psychiatrist, assumed the Presidency of the Faculty; and T. Donald Lewers MD, an Easton Internal Medicine specialist, was elected President-elect. In a contest for election to the Board of Medical Examiners, the nominees presented by the Nominating Committee were elected to a four-year term. They were C. Earl Hill MD, Pasadena; and Rose Mary Bonsack MD, Aberdeen.

Various members were given Emeritus status in the Faculty; awards were made to photo contest winners. Roland T. Smoot MD, Baltimore, immediate past-president, was given an award for Community Service.

Presentations of unrestricted funds in varying amounts were made to representatives of the three Maryland Medical Schools. Fifty-year certificates were presented to qualifying members.

Council adopted the recommendations of the Reduction of Cholesterol Levels Task Force and also approved the Faculty acting as the issuer and holder of common ID numbers for physicians, required under legislation enacted at the 1985 General Assembly session. Elected as Council Chairman was Leon K. Kassel MD, Baltimore; Leslie R. Miles MD, Cumberland, was elected Vice-Chairman.

JOHN SARGEANT
Executive Director

Use of 24-hour pH Monitoring for Gastroesophageal Reflux

SALAH M. NASRALLAH MD

Gastroesophageal reflux is a known cause of heartburn, epigastric pain, and chest pain. These symptoms may be secondary to esophagitis, and acid-sensitive esophagus, or esophageal motor disturbance. Several physiologic factors play a role in inhibiting gastroesophageal reflux including pressure in the lower esophageal sphincter, esophageal peristalsis, and salivary secretions.[1–7] Any process that may alter these protective mechanisms may result in potential damage to the esophageal mucosa.

Dr. Nasrallah is with the Division of Gastroenterology, Department of Medicine, University of Maryland Hospital, 22 S. Greene St., Baltimore, MD 21201.

The lower esophageal sphincter (LES), being in a state of tonic contraction, provides a barrier against reflux in the normal individual. In addition, the esophageal peristaltic contractions help in clearing any residual acid in the esophagus within several seconds. The alkaline pH of the saliva neutralizes residual acid efficiently, providing another protective mechanism.

Factors Predisposing to Reflux

Many factors may interfere with the pressure in the LES;[8] these are summarized in Table 1. By far, the most frequent causes are smoking, advancing age, and certain systemic diseases. Contrary to general belief, the presence of hiatal hernia is not an indication of impaired lower esophageal sphincter pressure.

Conditions that interfere with the normal peristalsis of the esophagus also may predispose to gastroesophageal reflux and/or inability of the esophagus to clear the acid. Some of these conditions are summarized in Table 2 and include conditions that affect smooth and skeletal muscles or their nerve supply. Impairment of peristalsis in the lower esophagus is more common than upper esophageal damage and may result from scleroderma, diabetes mellitus, chronic alcohol abuse, advancing age, and certain medications such as nitrates, calcium channel blockers, and hydralazine.

Delayed gastric emptying or gastric outlet obstruction also may predispose to gastroesophageal reflux.

Consequences of Reflux

Frequent reflux of acid into the esophagus and impairment of esophageal acid clearance may lead to the development of esophagitis, ulcerations in the lower end of the esophagus, Barrett's esophagus, and esophageal strictures. Reflux occurs most commonly when the patient is in an unconscious state, as during sleep. Aspirations may occur leading to bronchiectasis, chronic bronchitis, and asthma, particularly in children.[9–11] Thus, it is extremely important to assess whether gastroesophageal reflux is present in any of these conditions (Table 3).

Table 1. Factors that Reduce LES Pressure

Smoking
Progesterone
Pregnancy
Anticholinergics
Nitrates
Calcium channel blockers
Scleroderma
Diabetes mellitus
Aging

Table 2. Factors that Reduce Esophageal Clearance

Lower Esophagus
Scleroderma
Diabetes mellitus
Aging
Chronic alcoholism
Nitrates, calcium channel blockers, hydralazine
Intestinal pseudo-obstruction
Chaga's disease

Upper Esophagus	
Neurogenic	**Muscular**
Cerebrovascular	Mytonia dystrophica
Multiple sclerosis	Muscular dystrophy
AML	Polymyositis
Huntington's	Amyloidosis
Diphtheria	Thyrotoxicosis
Tetanus	Myxedema
Polyomyelitis	Myasthenia gravis

Table 3. Complications of GE Reflux

Esophageal
Esophagitis
Esophageal ulcers
Esophageal strictures
Barrett's esophagus
Pulmonary
Chronic bronchitis
Bronchiectasis
Asthma

Tests for Gastroesophageal Reflux

Various methods have been advanced for assessment of gastroesophageal reflux and the persistence of acid in the esophagus,[12,13] including simple observation during a barium swallow to document the presence of reflux. Evaluation of reflux may be made with a pH electrode swallowed by the patient and positioned 5 cms above the lower esophageal sphincter. The pH is continuously recorded. If reflux occurs, the pH of the esophagus drops below 4. This would be spontaneous reflux and is the most severe type. If spontaneous reflux does not occur, various maneuvers that increase intra-abdominal pressures are performed. If, despite these maneuvers reflux does not occur, then the stomach is filled with dilute acid and the pH recording continued with and without provocative maneuvers. These maneuvers measure the competence of the LES, but do not document reflux that may occur under other circumstances and do not correlate the presence of reflux to the occurrence of pain.

These limitations and the frequent occurrence of reflux at a time when the patient is asleep led to the development of 24-hour pH monitoring by Johnson and Demeester.[14] This system has been modified for outpatient use[15] and consists of a portable, battery powered pH data logger and a control computer unit for high-speed recovery of the logged pH data. The microprocessor measures the total time below pH 4, number of episodes of reflux, average duration, and duration of longest period of reflux. The patient denotes pain, heartburn, eating, wheezing, and so on, with a push-button event marker so correlation with pH is possible. The instrument also has a built-in tilt switch that senses and logs when the patient lies down.

With this system, episodes of pain or heartburn can be correlated with the presence or absence of gastroesophageal reflux. Thus, a cause-and-effect relationship may be established. Also, the position in which reflux occurs is noted so that decisions on therapy can be made.[16,17]

Whether reflux is the cause of symptoms can be documented by the above procedure during the 24-hour pH monitoring period. Not all patients, however, require 24-hour pH monitoring, and often if reflux is demonstrated during a pH study as described above, documentation of the cause of pain may be done by performing an acid perfusion study. During this test, 0.1 N HCl is infused 5 cms above the LES through a nasal esophageal tube at a rate of 4 ml per minute. Invariably, patients who have an acid-sensitive esophagus will reproduce their symptoms within a period of five to six minutes. Pain occurring later than that may be nonspecific and may denote a false positive test.

Table 4. Indications for 24-hour pH Monitoring

Atypical chest pain
Pyrosis at night
Stricture with negative work-up
Pulmonary symptoms
Esophagitis responding poorly to therapy

Who Needs 24-hour pH Monitoring?

Twenty-four hour pH monitoring is indicated in patients suffering with atypical chest pain that wakes them up at night, symptoms of heartburn unresponsive to treatment, chronic pulmonary symptoms that are exacerbated at night, or in patients for whom surgery is contemplated, Table 4. In addition, 24-hour pH monitoring may be used in patients with benign esophageal strictures without documented reflux by regular pH studies.

What Can Be Done to Stop Reflux?

In the management of reflux, we follow a three-step approach. The initial management of these patients (step 1) is in the form of antireflux maneuvers. These include elevating the head of the bed, eating small meals, losing weight, and avoiding alcohol, chocolate, fatty foods, juices, smoking, and lying down for one to two hours after meals. In addition, we start antacids 30 ml, one and three hours after meals and at bedtime. If the patient continues to be symptomatic after one week of therapy, we add an H2 blocker such as cimetidine 300 mg q6h or ranitidine 150 mg b.i.d. If these strategems do not result in improvement after two weeks, we proceed with (step 2) a therapy that includes the use of metoclopramide in addition to the previously described antireflux maneuvers. Metoclopramide, in a dosage of 10–20 mg t.i.d., increases the amplitude of contractions and the lower esophageal sphincter pressure. Sometimes bethanecol in a dosage of 12.5 to 25 mg t.i.d. is used.

If the above maneuvers do not result in improvement and if one can document the presence of esophagitis, esophageal ulcers, or esophageal strictures, then it is justifiable to proceed (step 3) with an antireflux type of procedure.[18]

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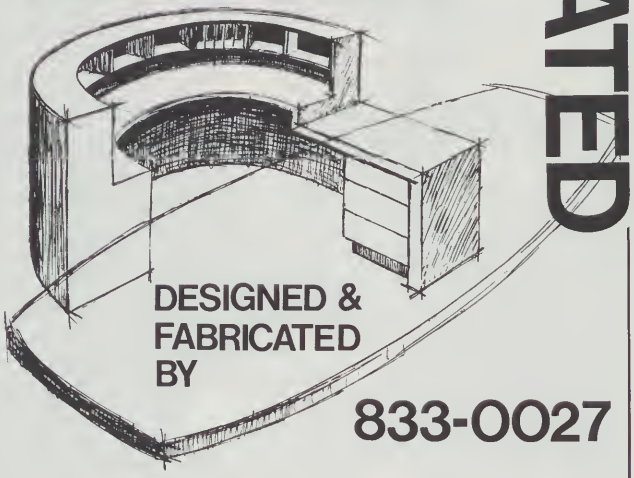
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Quantitative Assessment of Burn Wound Progress

RONALD E. GOANS MD

Use of high frequency ultrasonic pulse-echo methods has been demonstrated[1–4] to provide a sensitive measurement of tissue damage in model partial-thickness burns on Yorkshire pigs. An important result of these experiments is the first documentation of the conversion of a partial-thickness burn to a more severe injury through ischemia,[5] drying[6] or infection.[7–10] These results are directly applicable to clinical practice.

This work was performed at Oak Ridge National Laboratory, Health Physics Division, Oak Ridge, Tennessee. Dr. Goans is a resident in the Department of Obstetrics and Gynecology, Providence Hospital, 1150 Varnum St., NE, Washington, DC 20017.

In previous experiments designed to evaluate the use of ultrasound to measure burn depth,[11,12] contact burns at 100°C were placed on the dorsal surface of shaved Yorkshire pigs under general anesthesia. Yorkshire pigs were chosen for histological similarity to human dermis. The burning time ranged from 10 to 60 seconds. Sixteen different burns of varying severity were placed on six different Yorkshire pigs; the depth of each burn was monitored *in vivo* for several days postburn using high-frequency ultrasonic pulse-echo techniques. A total of 340 ultrasound measurements were taken including 68 determinations of normal dermal thickness on similar unburned areas of the experimental animals. Ultrasound depth measurements were taken at various times postburn, and the depth of necrosis was evaluated.

Standard, highly damped, broadband transducers with a peak frequency in the range 5–20 mHz were used. The pulse width was generally no more than 200 nsec, giving an axial depth resolution of less than 0.2 mm in soft tissue.

Biopsy specimens were taken frequently for microscopic confirmation of the *in vivo* measurements. These specimens were fixed immediately after excision by immersion in Millonig's phosphate buffer containing 0.1 percent EDTA, 3 percent sucrose, and 0.5 percent glutaraldehyde at pH 7.4. After several days fixation, the tissue was stained with Verhoeff's elastica stain and Van Gieson's counterstain. This stains the zone of coagulation necrosis deep purple; relatively normal dermis appears pink as is typical with a collagen stain, see Figure 1.

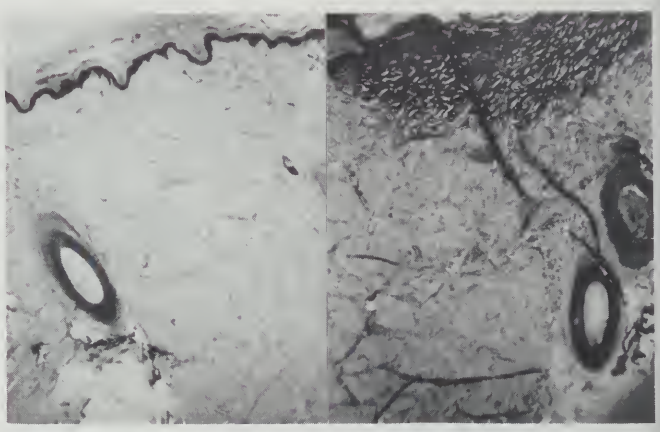


Figure 1. Normal porcine dermis (l). Partial thickness burn showing acoustic interface (r).

Results

A comparison of ultrasonic burn depth measurements with microscopic analysis of these sections confirmed that the ultrasonic technique was accurate to within 10 percent, and the 0.2 mm axial resolution was sufficient to distinguish partial-thickness burns from full-thickness burns in all cases.

An acoustic interface developed within a few minutes postburn. Depth of the interface below the skin surface could be reproducibly measured several days postburn. Depth of the necrotic layer was typically 1 to 2 mm, depending on burning time. From histological study this interface appears to correspond to a transition layer between a zone of coagulation necrosis and a zone of vascular stasis.[13–15]

Of the sixteen burns, six had a statistically significant increase in burn depth with time. In two cases the partial-thickness burn was observed to convert to a full-thickness injury. Data for a 30-second burn that converted to a full-thickness injury are shown in Figure 2, next page. The Table (next page) presents a standard linear regression analysis for each of the six cases along with determination of the level of significance of each result. The level of significance was calculated using the t statistic. Although conversion of burns from partial to full thickness has been observed clinically, these measurements represent the first documentation of this conversion.

After these experiments were performed, there was an opportunity to perform the measurement on a human. The patient, a 35-year-old male, had 30 to 40 percent total body burns from a car accident. A substantial part of the burned area was clinically determined to be full-thickness. The results of the measurement are given in Figure 3, next page, which compares pulse-echo spectra from burned and unburned areas of human skin. The top spectrum was taken from 21-day eschar on a full-thickness thigh burn; the bottom spectrum is from normal thigh tissue on the same patient. The measurement was performed with the patient im-

mersed in a Hubbard tank. From these data the eschar thickness was calculated to be approximately 1.1 mm.

Conclusion

High frequency ultrasound methods may be useful in monitoring changes in depth of necrotic tissue with time as well as providing for an initial determination of burn depth. Increased use of ultrasound in the burn ward should provide useful clinical information on progress of a wound. Early and frequent monitoring would permit rapid assessment of healing and early detection of complications, such as infection. Monitoring easily could be combined with any treatment regimen (such as the Hubbard tank) that incorporated immersion of the burned area. Careful attention to the results of an ultrasonic scan also may provide insight into the processes occurring at the microscopic level, giving the clinician more information for planning a course of treatment.

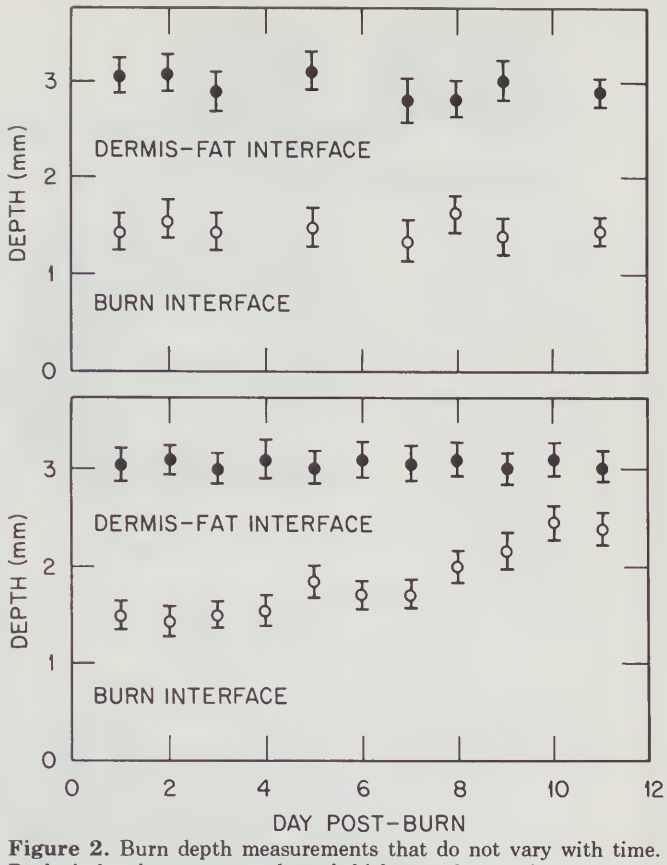


Figure 2. Burn depth measurements that do not vary with time. Dark circles show constant dermal thickness of approximately 3 mm (top). Burn depth measurement where burn converts from partial to full thickness injury (bottom).

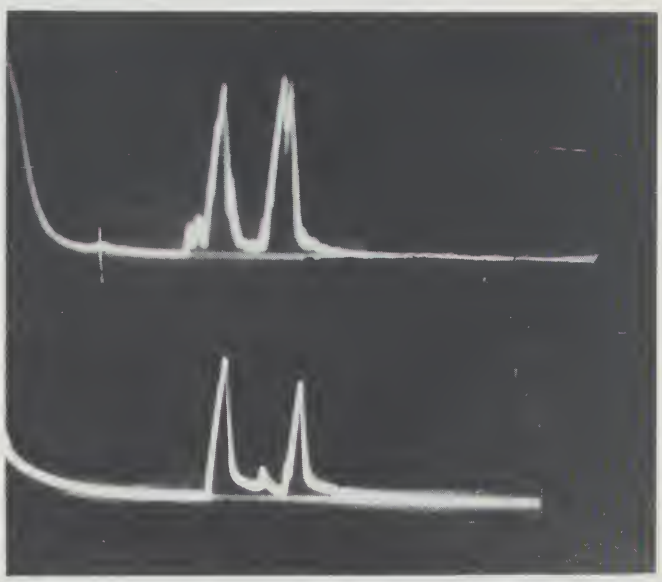


Figure 3. Burn depth measurement from 21 day eschar on a thigh burn (top). Measurement of unburned thigh dermis (bottom).

Acknowledgments

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Table. Regression Analyses for Six Cases

Case	Burn Time (sec)	Y-intercept (mm)	Slope (mm/day)	Correlation Coefficient, r	Level of Significance, p
1	30	1.11	0.12	0.94	<0.01
2	30	1.42	0.05	0.81	<0.05
3	20	1.16	0.05	0.80	<0.05
4	20	1.04	0.11	0.83	<0.05
5	45	1.58	0.08	0.60	<0.05
6	45	0.97	0.25	0.81	<0.05

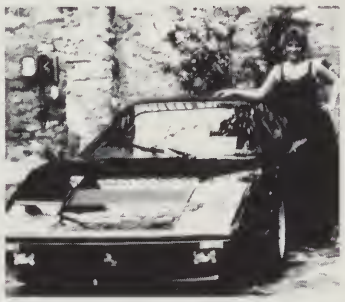
Normal dermal thickness = 3.1 ± 0.3 mm. Contact temperature was 100°C.

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Note: Culture and susceptibility tests should be initiated prior to and during therapy.

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WARNINGS: *Use cephalosporin derivatives with great caution in penicillin-sensitive patients since there is clinical and laboratory evidence of partial cross-allergenicity of the two groups of antibiotics; there are instances of reactions to both drug classes (including anaphylaxis after parenteral use).* In persons who have demonstrated some form of allergy, particularly to drugs, use antibiotics, including cephradine, cautiously and only when absolutely necessary.

Pseudomembranous colitis has been reported with the use of cephalosporins (and other broad spectrum antibiotics); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with antibiotic use. Treatment with broad spectrum antibiotics alters normal flora of the colon and may permit overgrowth of clostridia. Studies indicate a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis. Cholestyramine and colestipol resins have been shown to bind the toxin *in vitro.* Mild cases of colitis may respond to drug discontinuance alone. Manage moderate to severe cases with fluid, electrolyte and protein supplementation as indicated. Oral vancomycin is the treatment of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile* when the colitis is severe or is not relieved by drug discontinuance; consider other causes of colitis.

PRECAUTIONS: General: Follow patients carefully to detect any side effects or unusual manifestations of drug idiosyncrasy. If a hypersensitivity reaction occurs, discontinue the drug and treat the patient with the usual agents, e.g., pressor amines, antihistamines, or corticosteroids. Administer cephradine with caution in the presence of markedly impaired renal function. In patients with known or suspected renal impairment, make careful clinical observation and appropriate laboratory studies prior to and during therapy as cephradine accumulates in the serum and tissues. See package insert for information on treatment of patients with impaired renal function. Prescribe cephradine with caution in individuals with a history of gastrointestinal disease, particularly colitis. Prolonged use of antibiotics may promote the overgrowth of nonsusceptible organisms. Take appropriate measures should superinfection occur during therapy. Indicated surgical procedures should be performed in conjunction with antibiotic therapy.

Information for Patients: Caution diabetic patients that false results may occur with urine glucose tests (see PRECAUTIONS, Drug/Laboratory Test Interactions). Advise the patient to comply with the full course of therapy even if he begins to feel better and to take a missed dose as soon as possible. Tell the patient he may take this medication with food or milk since G.I. upset may be a factor in compliance with the dosage regimen. The patient should report current use of any medicines and should be cautioned not to take other medications unless the physician knows and approves of their use (see PRECAUTIONS, Drug Interactions).

Laboratory Tests: In patients with known or suspected renal impairment, it is advisable to monitor renal function.

Drug Interactions: When administered concurrently, the following drugs may interact with cephalosporins:

Other antibacterial agents — Bacteriostats may interfere with the bactericidal action of cephalosporins in acute infection; other agents, e.g., aminoglycosides, colistin, polymyxins, vancomycin, may increase the possibility of nephrotoxicity.

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Carcinogenesis, Mutagenesis: Long-term studies in animals have not been performed to evaluate carcinogenic potential or mutagenesis.

Pregnancy Category B: Reproduction studies have been performed in mice and rats at doses up to 4 times the maximum indicated human dose and have revealed no evidence of impaired fertility or harm to the fetus due to cephradine. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, use this drug during pregnancy only if clearly needed.

Nursing Mothers: Since cephradine is excreted in breast milk during lactation, exercise caution when administering cephradine to a nursing woman.

Pediatric Use: Adequate information is unavailable on the efficacy of b.i.d. regimens in children under nine months of age.

ADVERSE REACTIONS: Untoward reactions are limited essentially to G.I. disturbances and, on occasion, to hypersensitivity phenomena. The latter are more likely to occur in persons who have previously demonstrated hypersensitivity and those with a history of allergy, asthma, hay fever, or urticaria.

The following adverse reactions have been reported following use of cephradine: G.I. — Symptoms of pseudomembranous colitis can appear during antibiotic therapy; nausea and vomiting have been reported rarely. Skin and Hypersensitivity Reactions — mild urticaria or skin rash, pruritus, joint pains. Hematologic — mild transient eosinophilia, leukopenia and neutropenia. Liver — transient mild rise of SGOT, SGPT, and total bilirubin with no evidence of hepatocellular damage. Renal — transitory rises in BUN have been observed in some patients treated with cephalosporins; their frequency increases in patients over 50 years old. In adults for whom serum creatinine determinations were performed, the rise in BUN was not accompanied by a rise in serum creatinine. Others — dizziness, tightness in the chest, and candidal vaginitis.

DOSAGE: Adults — For respiratory tract infections (other than lobar pneumonia) and skin and skin structure infections: 250 mg q. 6 h or 500 mg q. 12 h. For lobar pneumonia: 500 mg q. 6 h or 1 g q. 12 h. For uncomplicated urinary tract infections: 500 mg q. 12 h; for more serious UTI, including prostatitis, 500 mg q. 6 h or 1 g q. 12 h. Severe or chronic infections may require larger doses (up to 1 g q. 6 h). For dosage recommendations in patients with impaired renal function, consult package insert.

Children over 9 months of age — 25 to 50 mg/kg/day in equally divided doses q. 6 or 12 h. For otitis media due to *H. influenzae*: 75 to 100 mg/kg/day in equally divided doses q. 6 or 12 h but not to exceed 4 g/day. Dosage for children should not exceed dosage recommended for adults. There are no adequate data available on efficacy of b.i.d. regimens in children under 9 months of age.

For full prescribing information, consult package insert.

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The Miasmatic and Microscopic Explanations for Disease in the European Past

VINCENT J. KNAPP PhD

No concept in the history of medicine lasted longer than the miasmatic explanation for the presence of disease. The idea began with Hippocrates around 400 B.C. and was discarded late in the nineteenth century as a direct result of the bacterial studies of German medical researcher Robert Koch.[1,2]

Dr. Knapp is Professor of History, State University of New York at Potsdam.

Hippocrates was convinced human diseases were caused by corrupt air currents. The basic assumption that physiological disorders were the result of poisonous substances lingering in the atmosphere was perpetuated by another Greek physician, Galen. Together, their arguments had a powerful influence on the educated elite of the Roman Empire and the Middle Ages;[3] the miasmatic or climatic explanation for disease was accepted virtually as dogma.

Although the miasmatic explanation was embroidered over time, the core remained essentially untouched. For centuries, explanations fell into the same vein: disease was caused by an inorganic substance moving through the air. This substance was referred to in medical literature as morbific matter, effluent, foul air, gas, or vapor.[4,5] On rare occasions the pythogenic theory was challenged by advocates of the microscopic explanation for the presence of disease.

By 1500 (the dawn of the modern era in European history) the miasmatic explanation was an old and venerated concept. Century after century it had powerful supporters. Numbered among these men was Girolamo Fracastoro. In time, Fracastoro questioned the completeness of the miasmatic point of view. However, Francastoro was convinced in the 1530s that "the source and seat of the evil [malignant syphilis] must exist in the air itself."[6] Scottish doctor Gilbert Skeyne said the same thing of bubonic plague, another disabling and deadly disease of sixteenth century Europe. He wrote: "Ane pest [the plague] is the corruptioun or infectioun of the Air ... [of] ane venemous qualytie and maist hurtfull Wapour thairof."[7]

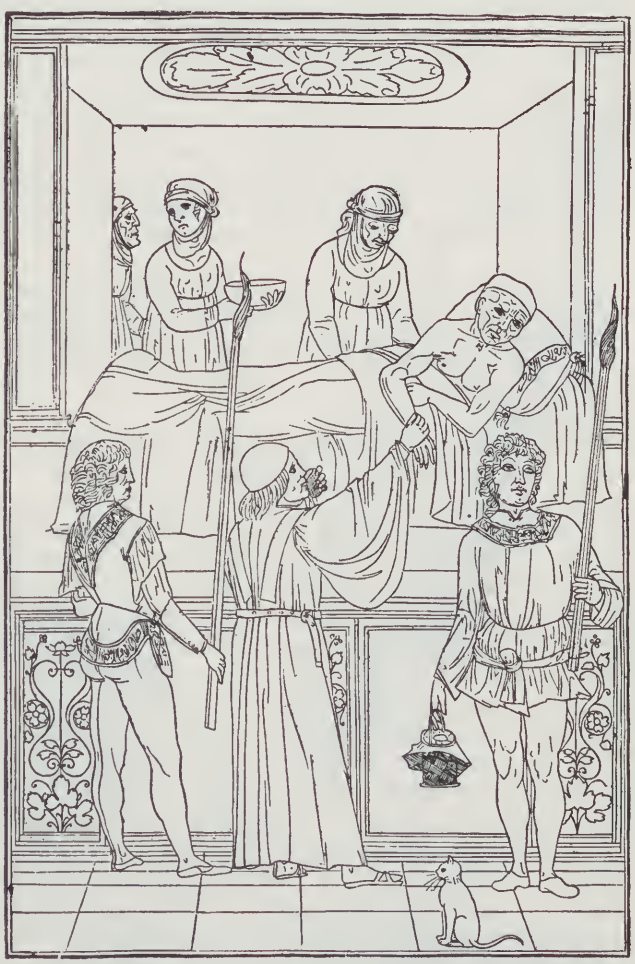
A century later Englishman William Kemp warned Londoners to beware of foul air. During the Great Plague of 1665 he advised,

> To guard your self from the corrupted air, you may do well, not to walk abroad till the Sun hath drawn up and disperst all foggy vapours, and to be within doors at Noon and the heat of the day, when the pores being more open, are apt to receive Infectious air.[8]

It seems few escaped the powerful intellectual grip that the miasmatic explanation had on Renaissance thinking. The concept was perpetuated further in the public mind by writers like Shakespeare. In *Timon of Athens* he threatened, "Jove Will o'er some high-vic'd City, hang this poison In the sick air."[9]

The miasmatic explanation dominated eighteenth century thought. Smallpox was ascendant over Europe; 85 percent of the population contracted the disease. English doctor John Haygarth pointed out smallpox was threatening the population through the air. Echoing others over the centuries, he said: "the natural small-pox appears to be *always* communicated thro' the air. Hence it be proved incontestibly that the pestilential effuvia, or *miasmas*, exist in the air near to a small pox patient."[10]

As the nineteenth century unfolded and the medical profession gained greater knowledge of both physiology



A doctor, feeling the pulse of a plague patient, protects himself by holding an impregnated sponge to his nose while his servants burn aromatics. Wood block from Johannes de Ketham, *Fasciculus Medicinae*. Venice: 1495.

and pathology, prevalent belief in the miasmatic explanation could be heard over and over again. Cholera came to Europe in the 1830s; the reason given for its presence was now more than 2,000 years old. In the words of Scottish medical observer James Keir, this new and terrible disease was

> induced by some deleterious vapour or gas, perhaps proceeding from the bowels of the earth, which mixing with our atmosphere and applied to the body, or inhaled into the lungs, exerts its deleterious influence on the blood and vital organs.[11]

Inconsistency within Theory

The only serious challenge to the miasmatic explanation was that not everyone caught in the midst of an epidemic came down with the disease. Since all people involved presumably were breathing the same infected air, this was an apparent inconsistency. The philosophical dilemma was solved by British physician Theophilus Lobb in the 1740s. He argued persuasively in defense of miasmas that the air was not equally saturated by poison. According to his calculations, morbid matter in the atmosphere existed unevenly; this explained why some people came down with the disease and others living a block away did not. As he expressed it:

> the Danger of being infected . . . very much depends on the Quantity of the infected Matter emitted into the Air, and the Nearness of Persons to receive it, before it is so much diluted with . . . [uncontaminated] Air, as to have lost its Powers of producing the Distemper.[12]

The predominance of the pythogenic theory for the presence of disease in the European past did not constitute a total monopoly. Another explanation circulated; while often unheeded, it was expressed occasionally. The microscopic explanation for the presence of disease fortunately was kept alive by a handful of medical thinkers until the nineteenth century when it finally prevailed. Three names stand out in this rather subterranean story (in chronological order): Girolamo Fracastoro, Athanasius Kircher, and Benjamin Marten.

Italian doctor Girolamo Fracastoro, writing in the 1530s, was the first Western thinker to espouse the germ theory. Discussing syphilis and its obviously contagious character, he argued that disease was caused by tiny, invisible creatures, which he continuously described as "seminaria." He further insisted that these minute substances could be passed from one person to another. Not only did he describe the process of contagion, but even more astonishingly he calculated that these seminaria had organic life of their own.[13] In one of the most famous passages in the history of medicine. Fracastoro declared:

> Contagion is a precisely similar putrefecation which passes from one thing to another, its germs [he mostly called them seminaria] have great activity, they are made up of a strong and vicious combination, and they have not only a material but also a spiritual antipathy to the animal organism.[14]

Fracastoro was amazingly close to the modern microscopic explanation for disease centuries before the theory was accepted universally.

Germ Theory

Fracastoro's thinking faded into insignificance in the decades after the 1530s. However, in the middle of the seventeenth century the germ theory was proclaimed loudly by a German Jesuit priest, Athanasius Kircher. There is no evidence that Kircher knew of Fracastoro's writings. Nonetheless, his thoughts on the etiology of disease were similar to those of his Italian predecessor. Like Fracastoro, he believed disorders in humans were caused by tiny, indiscernible substances known as animate effuvia; these substances originally were inorganic but

> under the influence of ambient heat and in proportion to the degree of infectious decomposition, [these] . . . animata effuvia . . produce an offspring of innumerable imperceptible worms, so that the more [of these] corpuscles [that] are present in the effuvia, . . . [the more] they may be considered no longer as evidence of life but as actual living effuvia.[15]

Kircher did not have the sophisticated biological language of the twentieth century to communicate his ideas. Still, he too was right about the germ theory. For example, he argued that "animata effuvia" were invisible and eventually alive. Kircher went beyond Fracastoro, correctly insisting these invisible objects were capable of proliferation and were subject to temperature.[16]

In the eighteenth century, an occasional voice was raised in favor of the microscopic explanation. Published in 1722, English doctor Benjamin Marten's writings are memorable; like Fracastoro and Kircher, his comments about the germ theory were close to the truth. He insisted disease was caused by invisible organisms, which he described as "wonderfully minute living creatures that . . . are inimicable to our Nature . . . [and are] capable of subsisting in our Juices and Vessels."[17] The germ theory persisted as, at best, a weak echo. In the early 1770s, Russian doctor Danilo Samoilovich discarded it as an explanation for the presence of plague in Moscow. He found the notion as contrary to the medical profession's view of the nature of things.[18]

For centuries, the microscopic explanation for the presence of disease was relegated to the position of

mere speculation and hearsay in European society. Into the nineteenth century it fortunately was kept alive by highly imaginative men and by rumor. During that century, Filippo Pacini, Jean-Antoine Villemin, and Robert Koch married the microscopic explanation to readily observable bacterial evidence[19–21] and in the process, eliminated the miasmatic explanation. The medical profession finally disproved a theory that for 23 centuries had stood as the authoritarian explanation for the origin of disease.

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Seventeenth century microscope. From Robert Hooke, *Micrographia,* 1667.

Medical Miscellany

Maryland Commission on Hereditary Disorders
Maryland State Department of Health and Mental Hygiene

The Commission on Hereditary Disorders has prepared guidelines for a diagnostic protocol for physicians who screen maternity patients for alpha fetoprotein (AFP) to detect neural tube defects in the fetus. Eventually, the guidelines will become regulations under authority of the Commission.

Regulations are in effect for laboratories that perform the AFP screening test to ensure the reliability of their test data. However, elevations in AFP, or false positive results, unrelated to a neural tube defect can occur. Thus, a diagnostic protocol is recommended for appropriate follow-up of the AFP elevation prior to any intervention.

Guidelines: Screening for Neural Tube Defects in the Fetus

Open neural tube defects occur approximately once in 1,000 births in the United States. Among the most frequent are anencephaly, which is not compatible with extrauterine survival, and spina bifida, which results in paralysis of the lower extremities and impairs bladder and bowel control in almost all affected infants. Complications include hydrocephalus and mental retardation. Exact causes of neural tube defects are unknown. Evidence for a hereditary role in a few cases is provided by the likelihood (about one in 20) of recurrence once a family has had one affected infant.

Most infants with neural tube defects are born into families without a previous history. In the absence of a family history, prenatal screening, which gives women the option of terminating their pregnancy if the diagnosis of neural tube defect is confirmed, reduces the occurrence of neural tube defects. For women who elect not to terminate the pregnancy, knowledge that the fetus is affected can influence perinatal management, possibly resulting in a better outcome for the infant.

Elevations of maternal serum alpha-fetoprotein (MSAFP) between the 16th and 18th week of pregnancy are observed in 80–90% of open neural tube defects and in 3–5% of infants without neural tube defects. Because the defects occur only about once in 1,000 pregnancies, this means that for every woman with an affected fetus approximately 30–50 pregnant women with unaffected fetuses will also have positive tests. **In order to avoid termination of pregnancies in which the fetus does *not* have a neural tube defect, confirmatory tests must be performed.**

As most women in whom the MSAFP concentration is elevated will not be aware of what neural tube defects are (having had no previous family experience with them), they must have access, through their physicians, to information about the range of severity of neural tube defects as well as about the nature of confirmatory tests, including sonography and amniocentesis that may be needed to establish a diagnosis. **Trained counselors and facilities for prenatal diagnosis, must be available when MSAFP testing is undertaken.**

Before blood is collected for the MSAFP test, the pregnant woman should be informed of the options available to her should a diagnosis of neural tube defect be established; some women would choose not to have the test once they knew the options. Maryland law also requires informed consent for hereditary disorders testing. **Informed consent must be obtained prior to performing any invasive procedure for screening for neural tube defects including collection of blood for MSAFP testing.**

The Commission on Hereditary Disorders has had a long-standing concern about AFP screening and is issuing these guidelines in coordination with the regulations promulgated by the Laboratories Administration to ensure safe and effective use of MSAFP testing and other procedures in pregnant women in the State of Maryland. They are directed to physicians and others providing care to pregnant women.

Recommended Guidelines

1. Physicians and others planning to offer MSAFP screening for neural tube defects should make informational brochures available to pregnant women before obtaining their consent to perform any invasive test.

2. Brochures should describe neural tube defects and the reasons for AFP testing, including a description of the options available following the establishment of a diagnosis of neural tube defect. The brochures should also indicate that a positive MSAFP test alone does not establish a diagnosis and that confirmatory tests are needed.

3. Before performing any invasive procedure the physician should obtain the consent of the woman in writing and retain her consent as part of the woman's medical record.

4. Testing Procedures

Specimens should be sent only to laboratories that are in compliance with the Laboratories Administration regulations governing AFP tests for Neural Tube Defects (COMAR 10.10.05).

5. Screening Protocol

The general sequence in prenatal screening for neural tube defects includes the following steps:

a. The MSAFP test is to be performed between 16–18 weeks of gestation calculated from the first day of the last menstrual period.

b. If the first MSAFP is above the cutoff level, a repeat (second) serum AFP test is performed no later than the 20th week of gestation.

c. If the second AFP test is elevated, ultrasonography is to be used to determine whether the test results can be explained by incorrect estimate of gestational age, multiple fetuses, fetal death, apparent neural tube defect or other fetal pathology such as oomphalocele, gastroschisis, or congenital nephrosis.

d. If the elevated AFP level remains unexplained, amniocentesis should be performed before the 2nd week of gestation and the amniotic fluid AFP level measured.

e. If the laboratory reports the presence of fetal blood in the amniotic fluid, and the AFP is elevated, amniocentesis should be repeated 7–10 days later. If the AFP level in the amniotic fluid remains elevated, the physician may conduct additional studies, such as amniography or more extensive ultrasonography, to confirm or rule out suspected NTD.

f. An Acetylcholinesterase test should be performed on all amniotic fluids with elevated AFP levels. Elevations of both amniotic fluid alphafetoprotein and acetylcholinesterase aid in establishing a diagnosis of neural tube defect.

g. Information and counseling should be provided to the patient throughout the testing to enable her to make informed choices about whether to proceed with the testing, to understand the results, and the options available to her.

6. Maternal serum AFP screening is not recommended if the mother or father have any sibling, parent or previous child with a neural tube defect. This places the mother in a high risk category for having a fetus with a neural tube defect. The mother should be referred to a prenatal diagnostic center for counseling.

PHYSICIAN PLACEMENT SERVICE

The Medical and Chirurgical Faculty of the State of Maryland maintains a Placement Service for the convenience of Maryland physicians, hospitals and communities in search of candidates for positions available in our state. A detailed description of such opportunities should be forwarded to the Physician Placement Service, 1211 Cathedral St., Baltimore, MD 21201; telephone 1-301-539-0872.

Physicians wishing to locate in Maryland are invited to submit a resumé to be kept on file with the Physician Placement Service. Candidates are requested to inform the Faculty when they are no longer available for consideration for opportunities which might be available in Maryland.

Journal announcements on the Classified Advertising page for Physician Placement Service are charged at the regular Classified Advertising rate.

Nutrition for Hemodialysis Patients

The National Kidney Foundation recently published a new brochure, *Nutritional Considerations for the Patient on Hemodialysis.* It was specifically designed for use in the physician's office as a brief overview of the types of nutritional modifications often imposed on persons being treated with hemodialysis. Another available brochure has been reprinted and slightly revised since last year, *Nutritional Considerations for the Patient Before the Initiation of Dialysis.*

These brochures can be obtained through the local or state affiliates of the National Kidney Foundation. For further information contact the National Kidney Foundation, 2 Park Avenue, New York, NY 10016.

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Corneal Transplant Donation

RICHARD M. SUSEL MD

When a patient dies, there is one suggestion a physician can make to the bereaved family that may help transform a completely negative situation into a time of compassionate giving. A final act of generosity is the donation of corneal tissue for transplant.

Dr. Susel is Medical Director and Chairman of the Medical Board, Eye Banks International, 505 Park Ave., Baltimore, MD 21201.

The first penetrating keratoplasty was done many years ago, and over the past 25 years there have been some wonderful innovations: the operating microscope; use of 10, 11, and 12 zero sutures; and development of fine surgical operating instruments that increased the success rate to as high as 95 percent in certain types of corneal diseases.

As the U.S. population ages, more and more people are in need of and will be helped by corneal transplantation. This one- to two-hour surgical technique is bringing sight to thousands of blind people.

The limiting factor of this excellent work is the availability of tissue at the right time in the right place. Over the years, Eye Banks International (headquartered in Baltimore) has been responsible for a number of innovations including use of Eye Bank technicians to perform tissue collection, distribution of excess tissue nationally and internationally, regular use of corneas preserved in M-K culture media, and on-premise manufacture of M-K culture media.

Eye Banks International also sponsored the nation's first medical examiner's law enacted by Maryland's legislature and now copied by ten other states, created the first of a series of comprehensive training films and related course material for Eye Bank technicians, published an Atlas for training technicians in slit-lamp examination of donor tissue, installed a nationwide toll-free number for surgeons' use when requesting corneal tissue, and installed a computer link between our East Coast and West Coast affiliates of the Eye Bank International system.

Fundamentals of Donation

Physicians must be sure of their commitment to organ donation and how invaluable it is. Families must be told the truth about the patient's clinical situation and about the physician's feelings. The physician must focus on what can be done to care for the family.

Certain points need to be discussed with the family or next of kin. Physicians should use comfortable and familiar words and phrases to cover these ideas in more or less this order:

1. After telling the family of the death, allow them to express their emotions.
2. Express your sympathy: tell them how this death feels to you and what their loved one has meant to you.
3. Offer them the opportunity to donate an organ, pointing out that some good can come from their tragedy.
4. Tell them the difference their precious gift can make in restoring someone's sight through transplantation or research.
5. List some facts they may need to know:
   - No one can tell removal has been done (rather than saying it is not disfiguring).
   - It does not cost anything.
   - It does not delay any funeral memorial plans.
   - All major religions support organ donation.
   - It is a confidential decision.
   - The Eye Bank will send a letter of acknowledgment to the family stating the difference the gift made in other people's lives.
6. Reassure them that you will support any decision they make.
7. Make a date to contact them if the family wants time to think about donation.
8. Thank them for their courage and willingness to listen to you during their grief. Offer your availability to answer any questions they may have in the future.

Family Questions

Families generally do not hear all the details told them during the critical situation of a relative's death. They have many fears about what organ donation may entail. No matter how much people have heard about the need for organ donation, they care little about who needs what parts.

Frequently families donate their loved one's organs when they realize it will help them diminish their sense of futility of this death; they see organ donation as something their loved one might want them to do. Families tend to accept the value of research as readily as the importance of transplantation.

Legal Requirements

In discussing possible corneal donation, physicians must speak with the legal next of kin. The Uniform Anatomical Gift Act clearly defines the order of kin as spouse, adult children, parents, siblings, party responsible for the body.

The decision of next of kin may be documented by

written permission, telegram, recorded phone consent, or written phone consent.

Donor Criteria

Eye tissue from all donors can be used regardless of age or cause of death. Nonseptic tissue will be used for transplantation while that from septic donors will be used in a variety of research and teaching programs.

For your personal Eye Donor Form return this to
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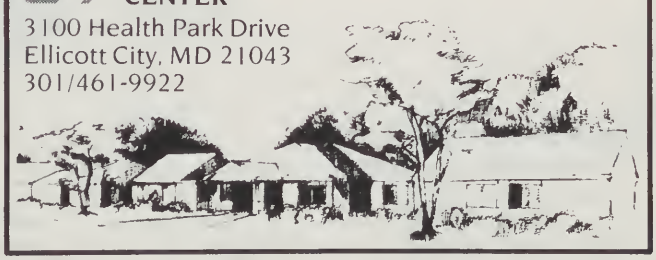
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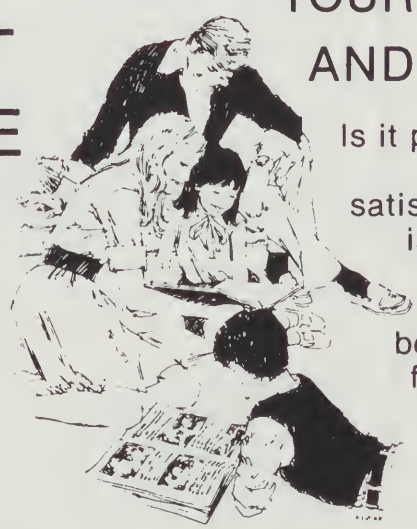
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Osteoarthritis IX: Biomechanical Factors, Prevention, and Nonpharmacologic Management

ANNELI H. NAVARRO MEd and JOAN D. SUTTON MSN

Questions regarding pathogenesis, natural history, and management of osteoarthritis remain unresolved and open to investigation. A diversity of factors (biochemical, inflammatory, immunologic, and biomechanical) may be involved in the process leading to osteoarthritis. After a review of biomechanical data related to the development of osteoarthritis, we discuss prevention and nonpharmacologic management of the patient with osteoarthritis.

Navarro is Assistant in Medicine and Sutton is Instructor in Medicine at The Johns Hopkins University, School of Medicine, in Baltimore.

Although osteoarthritic changes are most evident in articular cartilage, the subchondral bone is considered by many to be the primary site of injury.[1,2] Articular cartilage is thin; therefore most of the shock from mechanical loading of a normal joint is absorbed by the cancellous subchondral bone. Excessive mechanical stress, most frequently in the form of repetitive physiologic loading, rather than traumatic single impact loads, results in microfractures of the subchondral bone. Upon healing, this bone becomes stiffer and less able to absorb shock. As the shock absorption capacity of articular cartilage is limited, continued excessive loading of the joint leads to cartilage fibrillation, that is, fatigue failure of cartilage. At this stage remodeling of the bone with formation of osteophytes at the periphery of the joint takes place. Increased metabolic activity in the cartilage with efforts to repair itself has been described.[3,4] The arrest and sometimes reversal of the osteoarthritic process has been suggested by some investigators.[5]

This biomechanical model of excessive mechanical stress is corroborated by the clinical observation that osteoarthritis occurs primarily in weight-bearing and excessively used joints. Similar observations have been made in animals where mild but repetitive joint loading, such as walking on a concrete floor over a long period, has led to significant changes in bone and cartilage.[6]

Additional biomechanical models of osteoarthritis have been proposed where lack of mechanical stress, rather than excessive stress, is implicated as a causative factor. Hyaline cartilage has been compared to a water-filled sponge because 75 to 80 percent of its content, by weight, is fluid. For normal exchange of nutrients and waste material to take place between cartilage and synovial fluid, alternating compression and decompression of cartilage is required. Thus, joint motion and weight bearing serve a physiologic function necessary for cartilage nutrition and integrity.

Lack of joint loading is associated with an increase in the fluid content of cartilage, an early finding in osteoarthritis.[7] Osteoarthritic changes have been induced experimentally in laboratory animals following immobilization of a joint, compression of cartilage,[8] and resection of parts of a joint, the latter causing degenerative changes in the unopposed joint surfaces.[9,10] Furthermore, instability of the knee joint by resection of ligaments[11,12] and incongruence of the hip joint produced by extra-articular osteotomy[13] also have produced degenerative changes in laboratory animals.

Findings from immobilization studies can be summarized:

- degenerative changes in cartilage appear after 10 days of immobilization[14]
- there are cumulative degenerative changes from periodic immobilizations as brief as 4 days in duration at 4 week intervals[15]
- immoblization (periodic or continuous) over 30 days leads to progressive osteoarthritis[16]
- return to normal use and weight bearing after 3 weeks of immobilization reverses the effects of immobilization[17]
- excessive mechanical stress after 3 weeks of immobilization accelerates cartilage degeneration[18]

Prevention

Occupational and leisure activities can be analyzed for the type and amount of stress they exert on any joint or body segment.

The National Swedish Board of Occupational Safety and Health[19] has recommended that the following types of excessive mechanical stress associated with posture and body movements be avoided:

- prolonged tension of any one muscle
- awkward postures involving bent, twisted, or extended positions
- monotonous movements
- heavy lifting
- poor visual conditions
- vibration
- mental strain

The risk of injury is influenced by the type and amount of harmful physical stress as well as by the characteristics of the individual, including size, sex, age, fitness, and experience. The individual's perception of exertion is a good measure of physical strain and should serve as a guide to alter conditions.

For those unable to change the working situation, some relief can be obtained by providing opportunity for variation and recovery. For example, variation in

posture, patterns of movement, or pace of work will help reduce some of the strain. Equally important is the opportunity for recovery through well-spaced breaks. Shorter, more frequent rest periods provide more recovery than longer breaks taken less frequently. Also, frequent minibreaks of 2 to 30 seconds help reduce the strain from monotonous, fast-paced movements.

Management

Specific therapy to halt the progression of osteoarthritis has not yet been identified. Thus, physical measures based on a sound biomechanical foundation constitute an important part of the total management of the patient with this disease. It is important that physical measures be instituted early and implemented in an ongoing manner to derive the greatest possible benefits. The expertise of physical therapists and other members of the health care team need to be sought to provide the patient with necessary components of their care.

Nurses with expertise in rheumatology who function in office and ambulatory care settings may assume major responsibility for patients with degenerative joint disease. At the time of nurse management visits, the nurse is able to assess the musculoskeletal system, efficacy and side effects or untoward reactions of prescribed medications, the need for referral to other health care professionals, and the educational needs of both the patient and his or her family. In addition, a nurse is frequently in a position to monitor other coexisting health problems such as hypertension, diabetes, and vascular insufficiency. The needs of the individual with degenerative joint disease may be multifactorial and complex, and in some instances, may best be addressed by involvement in a nurse management program.

The following general principles of management should be considered:

1. Use Pain Relief Measures Pain when using the joint is one of the earliest manifestations of osteoarthritis. With advancing disease, pain also at rest is present, and in severe disease it may interfere with sleeping. Pain originating in the joint leads to protective tension of surrounding muscles, which, when continued, results in muscle fatigue and spasm, ischemia of muscle tissue, and more pain.

Heat is effective in providing temporary relief from pain and muscle spasm and frequently is used to prepare the patient for therapeutic exercise. Heat is preferred over cold in the absence of joint effusion and inflammation, particularly, when muscle spasm is a major cause of pain. The heat modalities selected for use at home should be safe, practical, and inexpensive. Patients often respond better to moist rather than dry forms of heat. Showering, bathing, or soaking involved parts in warm water are examples of moist heat modalities available in most homes.

Rest periods during the day with total absence of loading of the affected joint will help reduce pain and provide important periodic decompression of the affected cartilage.

2. Eliminate Excessive Loading of Joint Excessive loading of an osteoarthritic joint should be avoided at all times. Loading may be particularly harmful when the joint has been previously immobilized, as vigorous activity with loading of joint structures may further accelerate cartilage degeneration. The patient's daily activities should be analyzed for evidence of excessive joint loading.

Although there is no good evidence that obesity causes osteoarthritis, excess weight contributes to the abnormal loading of articular cartilage in weight-bearing joints. Obesity may aggravate symptoms and increase cartilage breakdown in the lower extremities and in the lumbar spine. To minimize excessive loading of joints, obese osteoarthritic patients should be instructed in weight-reduction. Loss of weight should provide symptomatic relief in addition to reducing synovial inflammation caused by cartilage breakdown.

Knees are most vulnerable to activities involving deep knee bends, including raising to standing unsupported by arms, where at the moment contact is lost with the chair, compressive forces equaling up to 7 times body weight act on the tibiofemoral joint.[20] Corresponding values for the patellofemoral joint can be as high as 7.6 times body weight.[21] Descending stairs, with active lengthening of the quadriceps muscle while maintaining tension, is particularly stressful on the patellofemoral joint.

Hips are more vulnerable to stair climbing than level walking with compressive forces of approximately 7, versus 3 to 4, times body weight in these two types of activities. While lifting a weight from the floor with flexed knees and burden close to the body is less stressful on the hips than lifting the same burden with straight knees, the former type of lift requires more flexibility in the hip joint.

Lumbosacral Spine is most vulnerable to compressive forces from lifting. The critical factor is body position rather than the weight of the burden. The flexed knee left with burden close to the body is the least stressful type of lift also on the lumbosacral joint, with a compressive force of 4.7 times body weight upon lifting a 12.8 leg weight.[22] The lowest L3 intradiscal pressure in sitting is obtained with lumbar spine well supported and in slight lordosis.[23]

3. Continue Physiologic Loading Loading of the articular cartilage through movement and weight bearing is necessary and therapeutic. Patients should understand the importance of continuing to engage in ordinary activities of daily life as long as excessively stressful activities have been eliminated and adequate rest is provided between activities. Patients should also understand the potential risks of inactivity. When weight-bearing pain is present, a cane and soft-soled shoes may be used to further reduce the impact of walking.

4. Maintain Flexibility and Strength Pain with accompanying reduction in the level of physical activity can be expected to cause eventual limitation of motion in the affected joint(s) and local as well as general loss of muscle strength. After a complete physical therapy evaluation, heat modalities combined with therapeutic exercise are used by physical therapists to address specific flexibility needs.

The type and amount of exercise to strengthen muscles surrounding an arthritic joint are selected on the basis of specific findings and patient tolerance. To reduce the strain and to enable patients to continue needed activities of daily life, an individually prescribed and periodically adjusted home exercise program is part of the total management. Attention also must be given to "optimizing" the strength of muscle groups needed for good posture, walking, rising to standing, and lifting.

Warm water in an accessible pool provides an ideal medium for therapeutic exercise under professional direction. Recreational swimming should be encouraged as an adjunct to therapy. Unsupervised participation in nonmedical health spa and fitness programs is potentially injurious and does not address the therapeutic needs of individuals with articular impairment.

5. Maintain Function Joint pain with muscle spasm, limitations of motion, muscle weakness, and inactivity constitute serious threats to the patient's ability to function. A complete functional assessment should include identification of skills and needs important to the patient. Physical therapists and occupational therapists possess expertise in the evaluation and training of locomotion, transfer, self-care, homemaking, and vocational skills. Emphasis is placed on highest possible level of function and independence under safe conditions.

Assistive devices are prescribed for safety, joint protection, and/or function. A wide range of assistive devices are currently available to meet many needs of the person with arthritis. Physical therapists and occupational therapists are trained to identify such needs, make appropriate recommendations, and train the patient in the proper use of a device.

The home environment may need to be evaluated for safety as many patients are elderly and may live alone. Bathrooms, stairways, and loose rugs are particularly dangerous for persons with locomotion problems.

6. Maintain Physical Fitness Essential components of fitness are cardiorespiratory endurance, muscular endurance, muscular strength, flexibility, balance and coordination/agility, all of which may decline as a result of osteoarthritis and a concomitant aging process. The unfit person tires easily and loses even more of the agility required for smooth, nonjarring movements. Such physical awkwardness magnifies the impact of physiologic loading adding trauma to affected joints.

Physical fitness activities should be encouraged and efforts should be made to develop a fitness program properly adjusted to the particular limitations of the patient yet appealing. Swimming, walking, ballroom dancing, stationary bicycling, rowing machine, and golfing provide important fitness benefits when done with regularity.

For patient education materials and information about programs for individuals with arthritis, contact the Arthritis Foundation, Maryland Chapter, 12 West 25th Street, Baltimore, MD 21218 301-366-0923.

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Hematuria from Metastatic Cancer to the Kidney: Case Report and Literature Review

MAY M. ALHASHIMI MD and STEVEN H. KRASNOW MD

The kidneys receive a fourth of the cardiac output, and hematogenous metastasis is common. However, clinical detection of secondary tumors of the kidney is uncommon when compared to necropsy findings. Metastatic carcinoma of the kidney is rarely diagnosed ante mortum.

Dr. Alhashimi is an Oncology Fellow, Oncology Section, Veterans Administration Medical Center, Washington, DC. Dr. Krasnow is Senior Staff Physician, Oncology Section, Veterans Administration Medical Center; Assistant Professor of Medicine, George Washington University, Washington, DC.

A 60-year-old black male was admitted to the medical service in November 1983 for painless hematuria. His history was significant for right upper lobectomy for squamous cell bronchogenic carcinoma in August 1983. The patient denied anorexia, weight loss, or increased cough.

Physical examination disclosed a thin black male in no acute distress. His blood pressure was 120/80; the pulse was 96/min. and regular; the respiratory rate was 18/min.; the temperature was 98°F.

Patient had poor dentition; a 3 x 3 cm ulcerative lesion in the left tonsillar region was noted, as well as a 2 x 2 cm left submandibular lymph node, which was fixed and nontender. Lungs were clear to auscultation and percussion. Abdominal examination revealed a liver palpable 4 cm below the right costal margin with a span of 13 cm by percussion; spleen tip was not palpable. The kidneys were not felt by bimanual palpation. Neurological examination was normal as were rectal and genitalia examinations.

Laboratory Data

CBC revealed a WBC 6500/mm^3 with a normal differential count; the hematocrit was 30 percent; the platelet count 202,000/mm^3. Routine chemistry screen was normal except for calcium of 12.4 mg/dL, and LDH of 377 mU/mL.

Urinalysis revealed gross blood; the specific gravity 1018; the pH 5; dipstick tests were positive for protein and negative for bile, ketones, and glucose. Microscopic examination revealed 10–15 WBCs, innumerable RBCs, and 10–15 epithelial cells per high power field.

Urine gram stain, bacterial culture, acid-fast bacilli smear, and culture were all negative. Urine cytology was negative for malignant cells.

Chest x-ray showed right apical scarring secondary to right upper lobectomy. No mass lesion or infiltrate was seen. A KUB film was normal. Biopsy of the tonsillar lesion revealed an infiltrating poorly differentiated squamous cell carcinoma. A bone scan was normal.

Intravenous pylogram showed a poorly defined right kidney outline, but no definite lesions. A renal 99 Tc scan showed irregular activity and cold defects in both kidneys indicating possible space-occupying lesions (Figure 1). A renal sonogram showed irregular lower poles of both kidneys and upper pole of left kidney, representing a possible solid mass lesion. There was a mild dilatation of the collecting system. CT scan of the abdomen is shown in Figures 2 and 3, next page.

The patient responded poorly to chemotherapy and died four months after admission. Autopsy exposed metastatic poorly differentiated squamous cell carcinoma involving left tonsillar area extending to the base of the epiglottis. The lobectomy site and other sites in lungs, epicardium, myocardium, and liver also were involved.

The kidneys were enlarged with external irregularly nodular surfaces, the cortex and medulla were studded with multiple necrotic nodules with cystic centers. The largest tumor nodule (measuring 3 x 4 cm) was in the lower pole of the right kidney. Microscopic examination revealed metastatic squamous cell carcinoma involving

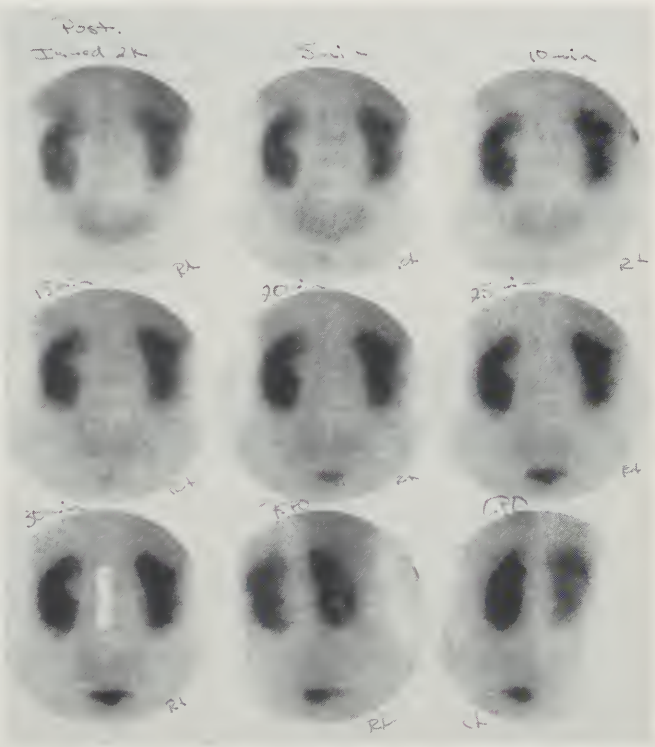


Figure 1. Renal 99 Tc scan showing multiple irregular cold defects in both kidneys.



Figure 2. Computerized tomography of the abdomen showing multiple mass lesions in both kidneys with a large necrotic mass in left kidney.

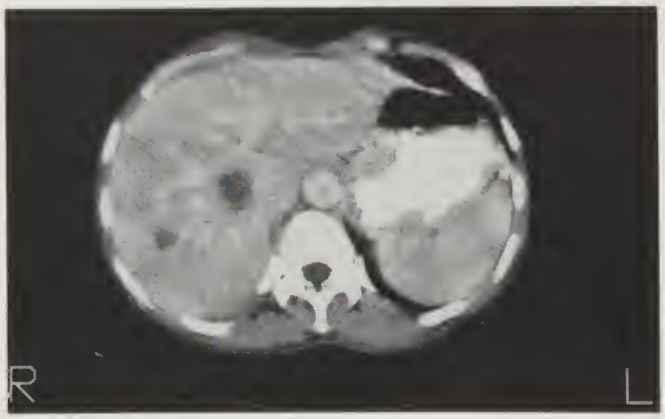


Figure 3. Computerized tomography of the abdomen showing two lesions in center of liver.

glomeruli, tubules, interstitium, and vessels with extensive necrosis.

Discussion

Our patient had metachronous primary carcinomas of the lung and tonsil. It is statistically more likely that metastases were from his recurrent lung tumor, since fewer patients with head and neck carcinomas develop metastatic disease.[1,2] Bronchogenic carcinoma is the most common solid tumor to metastasize to the kidneys.[3] Stomach and breast are the next most common primary sites.[4,5] Most secondary tumors do not distort the collecting system and do not produce discrete mass lesions as seen with primary tumors. Azotemia is not present unless there is a parenchymal destruction or ureteral obstruction by the tumor. The reason for lack of signs and symptoms in most cases is not clear.

In two large studies of successive autopsy records, Klinger[6] and Wagle[7] found the incidence of secondary kidney metastasis to be 2.4 percent and 1.8 percent respectively (see Table). In the 81 cases with kidney metastasis described by Wagle[8] none had renal pelvis involvement, all had permeation by tumor cells of renal lymphatics; capsular and stromal spread was noted in

Table. Summary of the Autopsy Reports Published

Author	Number of Autopsies	Number of Patients with Renal Metastasis	Number of Patients with Symptoms	Primary Site in Order of Frequency
Klinger[4]	5,000	118 (2.4%)	22 hematuria	lymphoma, lung,
Wagle[3]*	4,413	81 (1.8%)	2 flank pain 25 hematuria	stomach, breast lung, breast stomach
Olsson[9]**	315	60 (19.1%)	3 palpable mass or pain 7 hematuria	lung

* Cases of lymphoma were excluded from this study.
** All patients had primary bronchogenic carcinoma.

90 percent and 95 percent of patients respectively. Glomerular involvement was seen in only 6 percent of cases; the low incidence is attributable to the absence of lymphatics in glomerular region.

Olsson[9] reviewed the clinical records of 4,279 autopsies and found 315 cases of primary carcinoma of the lung. Sixty (19.1 percent) had renal metastases. Bilateral renal involvement was present in 36 of these cases (60 percent) and unilateral involvement in 24 cases (40 percent). The right kidney was more commonly affected with a ratio of 3 to 1.

A retrospective analysis of the clinical records of these 60 patients was done to determine whether there was antemortem evidence of renal lesions. Only 3 patients (5 percent) had flank mass or pain referable to the affected kidney. Seven patients (11.6 percent) exhibited gross or microscopic hematuria. The reason so few patients have hematuria may be, as Klinger suggests, that ulceration of pyelocaliceal mucosa is not likely to occur in secondary neoplasms of the kidney.

There have been 21 reported cases of secondary kidney metastases diagnosed antemortem by kidney biopsy or laparotomy for clinical presentations.[10–17] A palpable mass was noted in one patient, flank pain in 17 patients, and hematuria in 16 patients. Only 3 patients had painless hematuria.

Some major textbooks in internal medicine do not include secondary kidney tumors in the differential diagnosis of hematuria.[18,19] We believe secondary tumors to the kidney should be considered in patients at risk for common carcinomas known to metastasize to the kidneys.

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Survey and Opinion Briefs

The Elderly and Medical Care in America: Their Own Evaluation of Quality, Access and Cost

As the 1984 elections approached, debate over proposals for the funding of Medicare grew more intense. These discussions were often based on general perceptions of the position occupied by the elderly in American society and the way that position affects the medical care they receive.

When polled in August 1983, a majority of young Americans aged 18–34 indicated that the elderly are *unable* to get needed medical care. This widespread opinion is related to the view held by 80 per cent of these same respondents that not enough of society's resources are being directed to financial support for the elderly. In fact, of all sectors listed, financial support for the elderly is seen as most in need of additional funding.

But what of the opinions of the elderly themselves? How do they view the quality, access, and cost of care they receive, and how do their opinions compare with those of younger Americans?

Quality: For several years, the AMA has examined the public's satisfaction with various aspects of their last visit to a physician. These include evaluations that relate to quality: treatment by staff, physicians' explanations, medical care received, and an overall rating. A positive difference indicates greater satisfaction among the elderly.

	Percent Very Satisfied		
	Age 18–34	Age 65+	Difference
Treatment by staff	47	69	22
Doctor's explanations	49	68	19
Medical care received	54	75	21
Overall	44	66	22

All the above differences are highly significant statistically and show major divergence of opinion by age. The size of the difference indicates strongly that *the elderly in America evaluate the quality of care they receive much more highly than do younger Americans.*

Access: The AMA's annual public opinion survey also examined views toward time to get an appointment, time spent waiting in the office, and access to medical care.

	Percent Very Satisfied		
	Age 18–34	Age 65+	Difference
Waiting in office	34	55	21
Waiting to get an appointment	50	65	15
	Percent Agree		
The elderly are able to get needed medical care	48	64	16

Again, the elderly rate their access to medical care much more highly than respondents aged 18–34. Waiting times in the office and for an appointment are also evaluated more positively.

Cost: Several questions addressing cost issues were included in the 1983 survey.

	Percent Stating Not Enough Currently Being Spent		
	Age 18–34	Age 65+	Difference
Health care	58	44	14
Financial support for the elderly	80	53	27
	Main Problem Facing Medicine		
Cost	60	72	−12
	Percent Very Satisfied		
The fee that the doctor charges	21	29	8
	Percent Agree		
My doctor's fees are usually reasonable	69	79	10

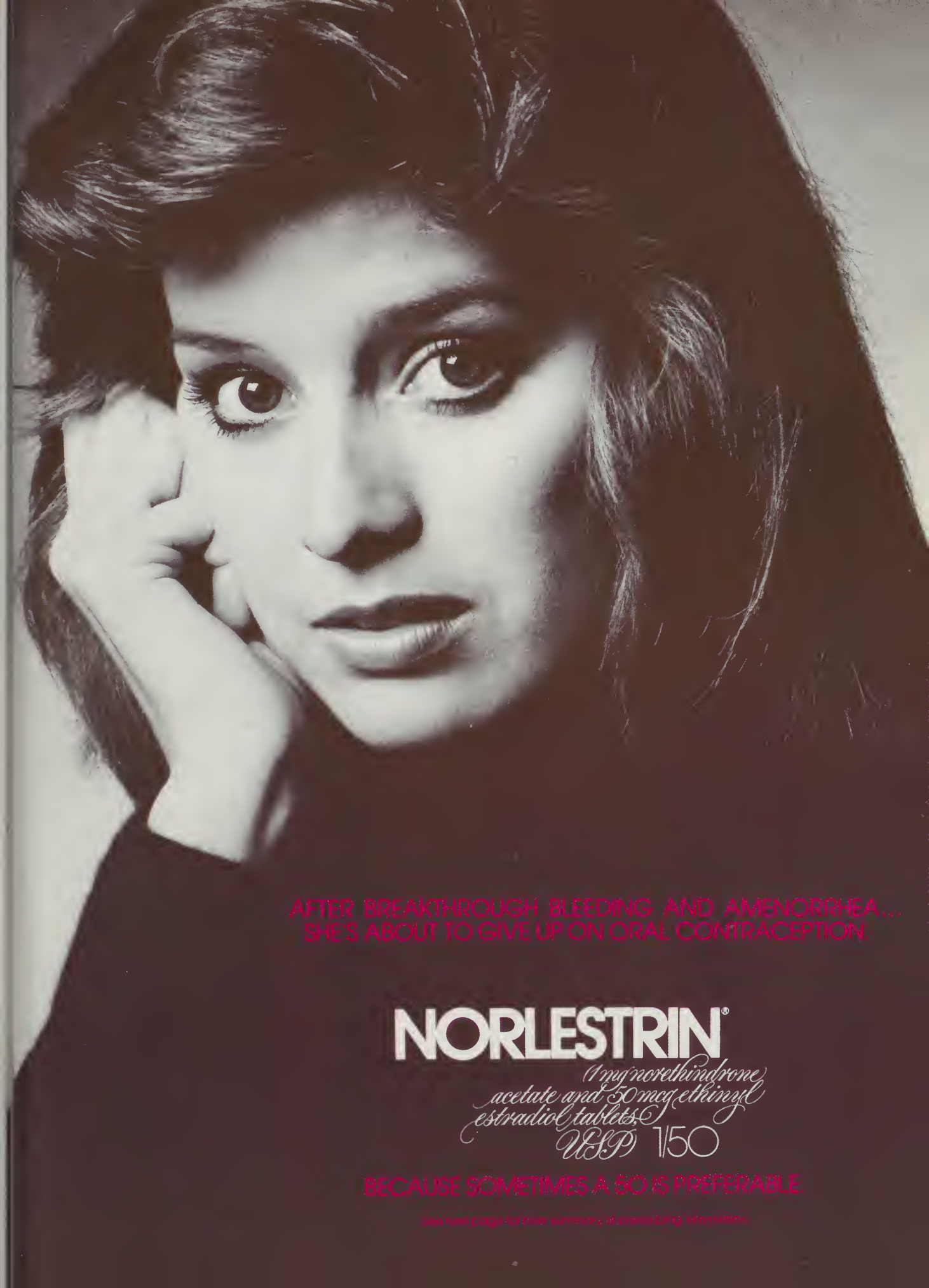
Several points emerge from these data. First, the elderly are much less likely than younger Americans to favor more spending on either health care *or financial support for themselves.* Second, in terms of actual experience, the elderly show higher levels of satisfaction with fees charged *and are more likely to view their own doctor's fees as reasonable.*

However, the elderly do exhibit heightened sensitivity to cost in general as the main problem facing health care. A possible explanation for this seeming inconsistency is that while current charges and expenditure levels are viewed relatively positively, because of fixed incomes, the elderly show increased sensitivity to the possibility of cost becoming a more pressing problem in the future. Fear of future change does not preclude relative satisfaction with current conditions.

Summary: Younger Americans have for a number of years held the very resistant opinion that the elderly face serious problems gaining access to quality medical care. The opinions of the elderly, based more accurately on their own experiences, show markedly higher evaluations of the quality of care they receive, their access to care, and less concern over the actual costs they incur. They do, however, indicate higher sensitivity to the general cost problem.

In general, this pattern of findings suggests that policymakers should carefully examine the specific opinions of groups involved in key issues rather than relying on general impressions in society that may not accurately reflect changing conditions.

If you have any questions or comments, contact Larry Freshnock, PhD, Director, Survey and Opinion Research (312-645-4450).


AFTER BREAKTHROUGH BLEEDING AND AMENORRHEA...
SHE'S ABOUT TO GIVE UP ON ORAL CONTRACEPTION.
NORLESTRIN®
1 mg norethindrone acetate and 50 mcg ethinyl estradiol tablets, USP 1/50
BECAUSE SOMETIMES A 50 IS PREFERABLE.
See next page for brief summary of prescribing information.

Brief Summary of Prescribing Information
NORLESTRIN® (norethindrone acetate and ethinyl estradiol tablets, USP)

See section under **Special Notes on Administration and HOW SUPPLIED.**
Before prescribing, please see full prescribing information. A Brief Summary follows.

DESCRIPTION
Norlestrin Products are progestogen-estrogen combinations

INDICATIONS AND USAGE
Norlestrin Products are indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

In clinical trials with Norlestrin 1/50 involving 25,983 therapy cycles, there was a pregnancy rate of 0.05 per 100 woman-years; in clinical trials with Norlestrin 2 5/50 involving 96,388 cycles, there was a pregnancy rate of 0.22 per 100 woman-years

Dose-Related Risk of Thromboembolism from Oral Contraceptives: Studies have shown a positive association between the dose of estrogens in oral contraceptives and the risk of thromboembolism. It is prudent and in keeping with good principles of therapeutics to minimize exposure to estrogen. The oral contraceptive prescribed for any given patient should be that product which contains the least amount of estrogen that is compatible with an acceptable pregnancy rate and patient acceptance

CONTRAINDICATIONS
1. Thrombophlebitis or thromboembolic disorders
2. A past history of deep-vein thrombophlebitis or thromboembolic disorders
3. Cerebral vascular or coronary artery disease
4. Known or suspected carcinoma of the breast
5. Known or suspected estrogen-dependent neoplasia
6. Undiagnosed abnormal genital bleeding
7. Known or suspected pregnancy (See WARNING No. 5)
8. Benign or malignant liver tumor which developed during the use of oral contraceptives or other estrogen-containing products.

WARNINGS

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

The use of oral contraceptives is associated with increased risk of several serious conditions including thromboembolism, stroke, myocardial infarction, hepatic adenoma, gallbladder disease, and hypertension. Practitioners prescribing oral contraceptives should be familiar with the following information relating to these risks

1. *Thromboembolic Disorders and Other Vascular Problems.* An increased risk of thromboembolic and thrombotic disease associated with the use of oral contraceptives is well-established. Studies have demonstrated an increased risk of fatal and nonfatal venous thromboembolism and stroke, both hemorrhagic and thrombotic.

Cerebrovascular Disorders: In a collaborative study in women with and without predisposing causes, it was estimated that the risk of hemorrhagic stroke was 2.0 times greater in users than nonusers, and the risk of thrombotic stroke was 4.0 to 9.5 times greater.

Myocardial Infarction: An increased risk of myocardial infarction associated with oral contraceptives has been reported confirming a previously suspected association. These studies found that the greater the number of underlying risk factors (cigarette smoking, hypertension, hypercholesterolemia, obesity, diabetes, history of preeclamptic toxemia) for coronary artery disease, the higher the risk of developing myocardial infarction, regardless of whether the patient was an oral contraceptive user or not. Oral contraceptives, however, were found to be a clear additional risk factor.

It has been estimated that users who do not smoke (smoking is considered a major predisposing condition to myocardial infarction) are about twice as likely to have a fatal myocardial infarction as nonusers who do not smoke. Oral contraceptive users who are smokers have about a fivefold increased risk of fatal infarction compared to users who do not smoke, but about a tenfold to twelvefold increased risk compared to nonusers who do not smoke. The amount of smoking is also an important factor.

Risk of Dose: In an analysis of data, British investigators concluded that the risk of thromboembolism, including coronary thrombosis, is directly related to the dose of estrogen used in oral contraceptives; however, the quantity of estrogen may not be the sole factor involved.

Persistence of Risk: Two studies have suggested that an increased risk may persist for as long as 6 years after discontinuation of oral contraceptive use for cerebrovascular disease and 9 years for myocardial infarction. In addition, a prospective study suggested the persistence of risk for subarachnoid hemorrhage.

Estimate of Excess Mortality from Circulatory Diseases: The risk of diseases of the circulatory system is concentrated in older women, in those with a long duration of use, and in cigarette smokers.

A study of available data from a variety of sources concluded that the mortality associated with all methods of birth control is low and below that associated with childbirth, with the exception of oral contraceptives in women over 40 who smoke.

The risk of thromboembolic and thrombotic diseases associated with oral contraceptives increases with age after approximately age 30 and, for myocardial infarction, is further increased by hypertension, hypercholesterolemia, obesity, diabetes, or history of preeclamptic toxemia, and especially by cigarette smoking.

The physician and the patient should be alert to the earliest manifestations of thromboembolic and thrombotic disorders. Should any occur or be suspected, the drug should be discontinued immediately.

A fourfold to sixfold increased risk of postsurgery thromboembolic complications has been reported in users. If feasible, oral contraceptives should be discontinued at least four weeks before surgery of a type associated with an increased risk of thromboembolism or prolonged immobilization.

2. *Ocular Lesions.* Neuro-ocular lesions, such as optic neuritis or retinal thrombosis, have been associated with the use of oral contraceptives. Discontinue the oral contraceptive if there is unexplained sudden or gradual, partial, or complete loss of vision; onset of proptosis or diplopia; papilledema; or retinal vascular lesions.

3. *Carcinoma.* Long-term continuous administration of estrogen in certain animal species increases the frequency of carcinoma of the breast, cervix, vagina, and liver.

In humans, an increased risk of endometrial carcinoma associated with the prolonged use of exogenous estrogen in postmenopausal women has been reported. However, there is no evidence suggesting increased risk of endometrial cancer in users of conventional combination or progestogen-only oral contraceptives.

Studies found no evidence of increase in breast cancer in women taking oral contraceptives; however, an excess risk in users with documented benign breast disease was reported.

There is no confirmed evidence of an increased risk of cancer associated with oral contraceptives. Close clinical surveillance of users is, nevertheless, essential. In cases of undiagnosed persistent or recurrent abnormal vaginal bleeding, appropriate diagnostic measures should be taken to rule out malignancy. Women with a strong family history of breast cancer, or who have breast nodules, fibrocystic disease, or abnormal mammograms, should be monitored with particular care.

4. *Hepatic Tumors.* Benign hepatic adenomas have been found to be associated with oral contraceptives. Because hepatic adenomas may rupture and may cause death through intra-abdominal hemorrhage, they should be considered in women presenting abdominal pain and tenderness, abdominal mass, or shock.

A few cases of hepatocellular carcinoma have been reported in women taking oral contraceptives. The relationship of these drugs to this type of malignancy is not known at this time.

5. *Usage in or Immediately Preceding Pregnancy; Birth Defects in Offspring; and Malignancy in Female Offspring.* During early pregnancy, female sex hormones may seriously damage the offspring.

An increased risk of congenital anomalies, including heart defects and limb defects, has been reported with the use of oral contraceptives in pregnancy.

There is some evidence that triploidy and possible other types of polyploidy are increased among abortuses from women who become pregnant soon after ceasing oral contraceptives.

Pregnancy should be ruled out before continuing an oral contraceptive in any patient who has missed two consecutive menstrual periods. If the patient has not adhered to the schedule, the possibility of pregnancy should be considered at the time of the first missed period, and oral contraceptives should be withheld until pregnancy has been ruled out. If pregnancy is confirmed, the patient should be apprised of the potential risks to the fetus and the advisability of continuation of the pregnancy should be discussed.

Women who discontinue oral contraceptives with the intent of becoming pregnant should use an alternate form of contraception for a period of time before attempting to conceive.

Administration of progestogen-only or progestogen-estrogen combinations to induce withdrawal bleeding should not be used as a test of pregnancy.

6. *Gallbladder Disease.* Studies report an increased risk of surgically confirmed gallbladder disease in users of oral contraceptives.

7. *Carbohydrate and Lipid Metabolic Effects.* Because decreased glucose tolerance has been observed in a significant percentage of patients, prediabetic and diabetic patients should be carefully observed while receiving oral contraceptives.

An increase in triglycerides and total phospholipids has been observed.

8. *Elevated Blood Pressure.* An increase in blood pressure has been reported in patients receiving oral contraceptives. The prevalence in users increases with longer exposure. Age is also strongly correlated with development of hypertension. Women who previously have had hypertension during pregnancy may be more likely to develop elevation of blood pressure.

9. *Headache.* Onset or exacerbation of migraine or development of headache of a new pattern which is recurrent, persistent, or severe, requires discontinuation of oral contraceptives.

10. *Bleeding Irregularities.* Breakthrough bleeding, spotting, and amenorrhea are frequent reasons for patients discontinuing oral contraceptives. In breakthrough bleeding, nonfunctional causes should be borne in mind. In undiagnosed abnormal bleeding from the vagina, adequate diagnostic measures are indicated to rule out pregnancy or malignancy.

Women with a past history of oligomenorrhea or secondary amenorrhea, or young women without regular cycles should be advised that they may have a tendency to remain anovulatory or to become amenorrheic after discontinuation of oral contraceptives.

11. *Ectopic Pregnancy.* Ectopic as well as intrauterine pregnancy may occur in contraceptive failures.

12. *Breast-Feeding.* Oral contraceptives may interfere with lactation. Furthermore, a small fraction of the hormonal agents in oral contraceptives has been identified in the milk of mothers receiving these drugs.

PRECAUTIONS

1. A complete medical and family history should be taken prior to the initiation of oral contraceptives. The pretreatment and periodic physical examinations should include special reference to blood pressure, breasts, abdomen, and pelvic organs, including Papanicolaou smear and relevant laboratory tests. As a general rule, oral contraceptives should not be prescribed for longer than one year without another examination.

2. Preexisting uterine leiomyomata may increase in size.

3. Patients with a history of psychic depression should be carefully observed and the drug discontinued if depression recurs to a serious degree.

4. Oral contraceptives may cause fluid retention and should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated.

5. Patients with a past history of jaundice during pregnancy have an increased risk of recurrence of jaundice. If jaundice develops, the medication should be discontinued.

6. Steroid hormones may be poorly metabolized and should be administered with caution in patients with impaired liver function.

7. Users may have disturbances in normal tryptophan metabolism, which may result in a relative pyridoxine deficiency.

8. Serum folate levels may be depressed.

9. The pathologist should be advised of oral contraceptive therapy when relevant specimens are submitted.

10. Certain endocrine and liver function tests and blood components may be affected: (a) Increased sulfobromophthalein retention. (b) Increased prothrombin and factors VII, VIII, IX, and X; decreased antithrombin 3; increased norepinephrine-induced platelet aggregability. (c) Increased thyroid-binding globulin (TBG) leading to increased circulating total thyroid hormone. (d) Decreased pregnanediol excretion. (e) Reduced response to metyrapone test.

Drug Interactions: Reduced efficacy and increased incidence of breakthrough bleeding have been associated with concomitant use of rifampin. A similar association has been suggested with barbiturates, phenylbutazone, phenytoin sodium, tetracycline, and ampicillin.

ADVERSE REACTIONS
An increased risk of the following serious adverse reactions has been associated with oral contraceptives: thrombophlebitis; pulmonary embolism; coronary thrombosis; cerebral thrombosis; cerebral hemorrhage; hypertension; gallbladder disease; benign hepatomas; congenital anomalies.

There is evidence of an association between the following conditions and the use of oral contraceptives, although additional confirmatory studies are needed: mesenteric thrombosis; neuro-ocular lesions, eg, retinal thrombosis and optic neuritis.

The following adverse reactions have been reported in patients receiving oral contraceptives and are believed to be drug related: nausea and/or vomiting, usually the most common adverse reactions, occur in approximately 10% or less of patients during the first cycle. Other reactions, as a general rule, are seen much less frequently or only occasionally: gastrointestinal symptoms; breakthrough bleeding; spotting; change in menstrual flow; dysmenorrhea; amenorrhea during and after treatment; temporary infertility after discontinuance of treatment; edema; chloasma or melasma; breast changes; change in weight; change in cervical erosion and cervical secretion; possible diminution in lactation when given immediately postpartum; cholestatic jaundice; migraine; increase in size of uterine leiomyomata; rash (allergic); mental depression; reduced tolerance to carbohydrates; vaginal candidiasis; change in corneal curvature; intolerance to contact lenses.

The following adverse reactions have been reported and the association has been neither confirmed nor refuted: premenstrual-like syndrome; cataracts; changes in libido; chorea; changes in appetite; cystitis-like syndrome; headache; nervousness; dizziness; hirsutism; loss of scalp hair; erythema multiforme; erythema nodosum; hemorrhagic eruption; vaginitis; porphyria.

Special Notes on Administration
Menstruation usually begins two or three days, but may begin as late as the fourth or fifth day after discontinuing medication.

After several months on treatment, bleeding may be reduced to a point of virtual absence; reduced flow may be a result of medication and not indicative of pregnancy.

HOW SUPPLIED
Norlestrin [21] 1/50 is available in compacts each containing 21 tablets. Each tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

Norlestrin [21] 2 5/50 is available in compacts each containing 21 tablets. Each tablet contains 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

Norlestrin [Fe] 1/50 is available in compacts each containing 21 yellow tablets and 7 brown tablets. Each yellow tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Each brown tablet contains 75 mg of ferrous fumarate, USP. Available in packages of five compacts and packages of five refills.

Norlestrin [FE] 2.5/50 is available in compacts each containing 21 pink tablets and 7 brown tablets. Each pink tablet contains 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Each brown tablet contains 75 mg of ferrous fumarate, USP. Available in packages of five compacts and packages of five refills.

Norlestrin [28] 1/50 is available in compacts each containing 21 yellow tablets and 7 white inert tablets. Each yellow tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

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Division of Warner-Lambert Company
Morris Plains, New Jersey 07950

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PD-21-JA-2563-P-1(11-84)

BALANCED CALCIUM CHANNEL BLOCKADE!



Low incidence of side effects
CARDIZEM® (diltiazem HCl) produces an incidence of adverse reactions not greater than that reported with placebo therapy, thus contributing to the patient's sense of well-being.

Reduces angina attack frequency*
42% to 46% decrease reported in multicenter study.[1]

Increases exercise tolerance*
In Bruce exercise test,[2] control patients averaged 8.0 minutes to onset of pain; Cardizem patients averaged 9.8 minutes ($P<.005$).

*Cardizem is indicated in the treatment of angina pectoris due to coronary artery spasm and in the management of chronic stable angina (classic effort-associated angina) in patients who cannot tolerate therapy with beta-blockers and/or nitrates or who remain symptomatic despite adequate doses of these agents.

References:
1. Strauss WE, McIntyre KM, Parisi AF, et al: Safety and efficacy of diltiazem hydrochloride for the treatment of stable angina pectoris: Report of a cooperative clinical trial. Am J Cardiol 49:560-566, 1982.
2. Pool PE, Seagren SC, Bonanno JA, et al: The treatment of exercise-inducible chronic stable angina with diltiazem: Effect on treadmill exercise. Chest 78 (July suppl):234-238, 1980.

CARDIZEM®
(diltiazem HCl)

THE BALANCED CALCIUM CHANNEL BLOCKER

Please see full prescribing information on following page.

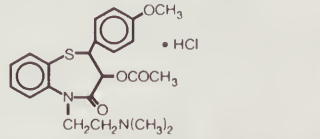
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PROFESSIONAL USE INFORMATION

cardizem®
(diltiazem HCl)
30 mg and 60 mg tablets

DESCRIPTION

CARDIZEM® (diltiazem hydrochloride) is a calcium ion influx inhibitor (slow channel blocker or calcium antagonist). Chemically, diltiazem hydrochloride is 1,5-Benzothiazepin-4(5H)one,3-(acetyloxy) -5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-, monohydrochloride,(+) -cis-. The chemical structure is:



Diltiazem hydrochloride is a white to off-white crystalline powder with a bitter taste. It is soluble in water, methanol, and chloroform. It has a molecular weight of 450.98. Each tablet of CARDIZEM contains either 30 mg or 60 mg diltiazem hydrochloride for oral administration.

CLINICAL PHARMACOLOGY

The therapeutic benefits achieved with CARDIZEM are believed to be related to its ability to inhibit the influx of calcium ions during membrane depolarization of cardiac and vascular smooth muscle.

Mechanisms of Action. Although precise mechanisms of its antianginal actions are still being delineated, CARDIZEM is believed to act in the following ways:

1. Angina Due to Coronary Artery Spasm: CARDIZEM has been shown to be a potent dilator of coronary arteries both epicardial and subendocardial. Spontaneous and ergonovine-induced coronary artery spasm are inhibited by CARDIZEM.
2. Exertional Angina: CARDIZEM has been shown to produce increases in exercise tolerance, probably due to its ability to reduce myocardial oxygen demand. This is accomplished via reductions in heart rate and systemic blood pressure at submaximal and maximal exercise work loads.

In animal models, diltiazem interferes with the slow inward (depolarizing) current in excitable tissue. It causes excitation-contraction uncoupling in various myocardial tissues without changes in the configuration of the action potential. Diltiazem produces relaxation of coronary vascular smooth muscle and dilation of both large and small coronary arteries at drug levels which cause little or no negative inotropic effect. The resultant increases in coronary blood flow (epicardial and subendocardial) occur in ischemic and nonischemic models and are accompanied by dose-dependent decreases in systemic blood pressure and decreases in peripheral resistance.

Hemodynamic and Electrophysiologic Effects. Like other calcium antagonists, diltiazem decreases sinoatrial and atrioventricular conduction in isolated tissues and has a negative inotropic effect in isolated preparations. In the intact animal, prolongation of the AH interval can be seen at higher doses.

In man, diltiazem prevents spontaneous and ergonovine-provoked coronary artery spasm. It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure and, in exercise tolerance studies in patients with ischemic heart disease, reduces the heart rate-blood pressure product for any given work load. Studies to date, primarily in patients with good ventricular function, have not revealed evidence of a negative inotropic effect; cardiac output, ejection fraction, and left ventricular end diastolic pressure have not been affected. There are as yet few data on the interaction of diltiazem and beta-blockers. Resting heart rate is usually unchanged or slightly reduced by diltiazem.

Intravenous diltiazem in doses of 20 mg prolongs AH conduction time and AV node functional and effective refractory periods approximately 20%. In a study involving single oral doses of 300 mg of CARDIZEM in six normal volunteers, the average maximum PR prolongation was 14% with no instances of greater than first-degree AV block. Diltiazem-associated prolongation of the AH interval is not more pronounced in patients with first-degree heart block. In patients with sick sinus syndrome, diltiazem significantly prolongs sinus cycle length (up to 50% in some cases).

Chronic oral administration of CARDIZEM in doses of up to 240 mg/day has resulted in small increases in PR interval, but has not usually produced abnormal prolongation. There were, however, three instances of second-degree AV block and one instance of third-degree AV block in a group of 959 chronically treated patients.

Pharmacokinetics and Metabolism. Diltiazem is absorbed from the tablet formulation to about 80% of a reference capsule and is subject to an extensive first-pass effect, giving an absolute bioavailability (compared to intravenous dosing) of about 40%. CARDIZEM undergoes extensive hepatic metabolism in which 2% to 4% of the unchanged drug appears in the urine. In vitro binding studies show CARDIZEM is 70% to 80% bound to plasma proteins. Competitive ligand binding studies have also shown CARDIZEM binding is not altered by therapeutic concentrations of digoxin, hydrochlorothiazide, phenylbutazone, propranolol, salicylic acid, or warfarin. Single oral doses of 30 to 120 mg of CARDIZEM result in detectable plasma levels within 30 to 60 minutes and peak plasma levels two to three hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3.5 hours. Desacetyl diltiazem is also present in the plasma at levels of 10% to 20% of the parent drug and is 25% to 50% as potent a coronary vasodilator as diltiazem. Therapeutic blood levels of CARDIZEM appear to be in the range of 50 to 200 ng/ml. There is a departure from dose-linearity when single doses above 60 mg are given; a 120-mg dose gave blood levels three times that of the 60-mg dose. There is no information about the effect of renal or hepatic impairment on excretion or metabolism of diltiazem.

INDICATIONS AND USAGE

1. **Angina Pectoris Due to Coronary Artery Spasm.** CARDIZEM is indicated in the treatment of angina pectoris due to coronary artery spasm. CARDIZEM has been shown effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (resting angina with ST-segment elevation occurring during attacks).
2. **Chronic Stable Angina (Classic Effort-Associated Angina).** CARDIZEM is indicated in the management of chronic stable angina. CARDIZEM has been effective in controlled trials in reducing angina frequency and increasing exercise tolerance.

There are no controlled studies of the effectiveness of the concomitant use of diltiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities.

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

1. **Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
2. **Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
3. **Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
4. **Acute Hepatic Injury.** In rare instances, patients receiving CARDIZEM have exhibited reversible acute hepatic injury as evidenced by moderate to extreme elevations of liver enzymes. (See PRECAUTIONS and ADVERSE REACTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS).

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vitro bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outweigh its potential risks in this situation.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences, as well as their frequency of presentation, are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%), AV block (1.1%). In addition, the following events were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrence.

Cardiovascular:	Flushing, arrhythmia, hypotension, bradycardia, palpitations, congestive heart failure, syncope.
Nervous System:	Paresthesia, nervousness, somnolence, tremor, insomnia, hallucinations, and amnesia.
Gastrointestinal:	Constipation, dyspepsia, diarrhea, vomiting, mild elevations of alkaline phosphatase, SGDT, SGPT, and LDH.
Dermatologic:	Pruritus, petechiae, urticaria, photosensitivity.
Other:	Polyuria, nocturia.

The following additional experiences have been noted:

A patient with Prinzmetal's angina experiencing episodes of vasospastic angina developed periods of transient asymptomatic asystole approximately five hours after receiving a single 60-mg dose of CARDIZEM.

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: erythema multiforme; leukopenia; and extreme elevations of alkaline phosphatase, SGDT, SGPT, LDH, and CPK. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

OVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with oral diltiazem has been limited. Single oral doses of 300 mg of CARDIZEM have been well tolerated by healthy volunteers. In the event of overdosage or exaggerated response, appropriate supportive measures should be employed in addition to gastric lavage. The following measures may be considered:

Bradycardia	Administer atropine (0.60 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.
High-Degree AV Block	Treat as for bradycardia above. Fixed high-degree AV block should be treated with cardiac pacing.
Cardiac Failure	Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics.
Hypotension	Vasopressors (eg, dopamine or levarterenol bitartrate).

Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating physician.

The oral LD_{50}'s in mice and rats range from 415 to 740 mg/kg and from 560 to 810 mg/kg, respectively. The intravenous LD_{50}'s in these species were 60 and 38 mg/kg, respectively. The oral LD_{50} in dogs is considered to be in excess of 50 mg/kg, while lethality was seen in monkeys at 360 mg/kg. The toxic dose in man is not known, but blood levels in excess of 800 ng/ml have not been associated with toxicity.

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3. **Beta-blockers.** (See WARNINGS and PRECAUTIONS.)

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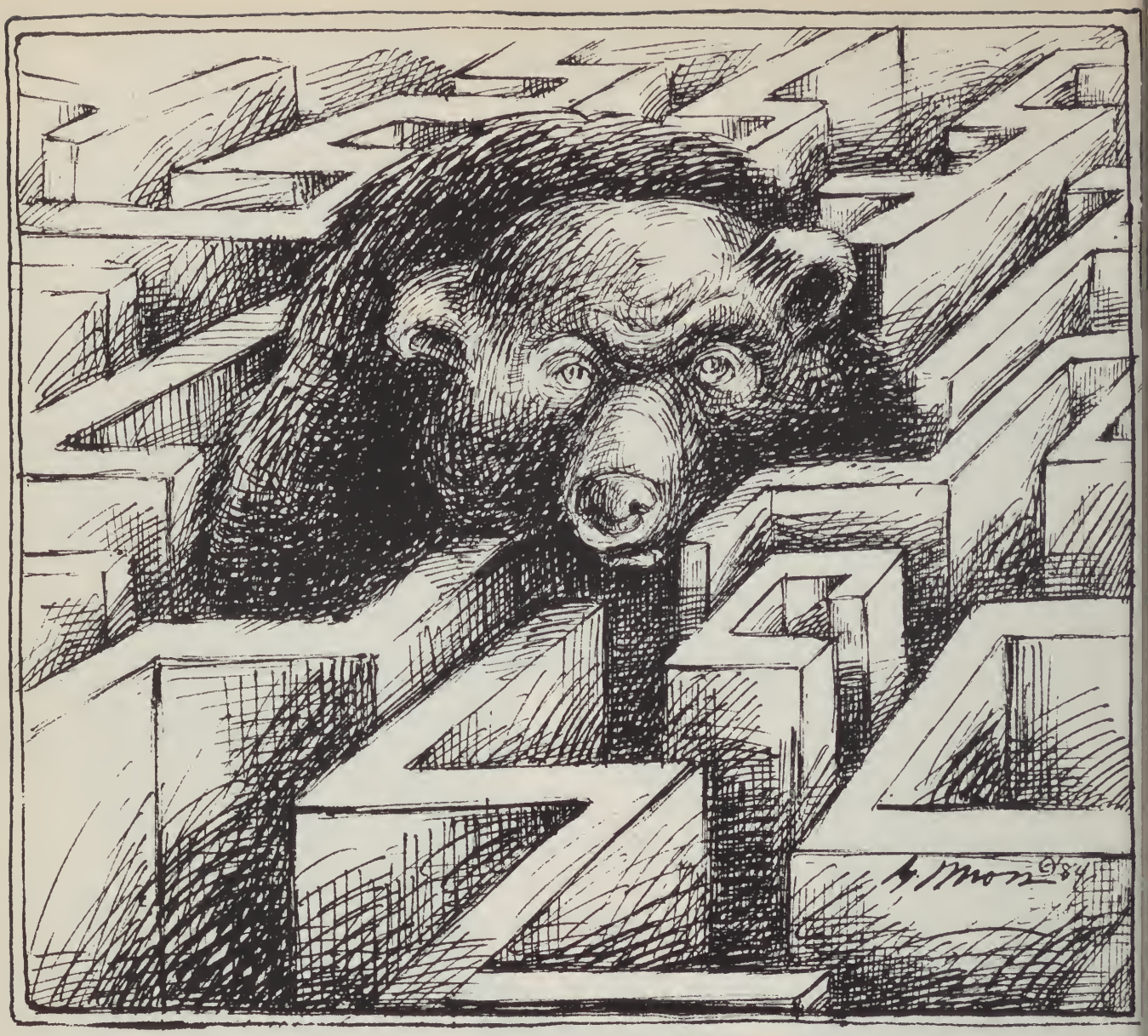
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Rehabilitation Medicine

The Dysfunctional Pain Patient—Returning to Work: A Preliminary Report

NORMAN B. ROSEN MD, KENNETH SHAROFF LCSW, and VIKRAM KHANNA MHS

The Dysfunctional Pain Patient (DPP) has been a source of great concern for health care providers. A model of treatment has proved successful in working with this patient population. Both inpatient and outpatient return-to-work rates demonstrate the effectiveness of this comprehensive and multidisciplinary model of treatment. The program was designed to provide a structured, intensive treatment experience.

Dr. Rosen is Medical Director, Rehabilitation and Pain Management Associates; Assistant Clinical Professor, Department of Rehabilitation Medicine, University of Maryland School of Medicine. Sharoff is Director, Social Work, Rehabilitation and Pain Management Associates; Faculty, Continuing Education Department, Sheppard Pratt Hospital. Correspondence: Dr. Rosen, Rehabilitation and Pain Management Associates, Ruxton Towers, Suite 204, 8415 Bellona Lane, Baltimore, MD 21204.

Acute and chronic pain of musculoskeletal origin is a frequent cause of patient visits to physicians. Of these, back and neck pain are among the most common causes of disability and time lost from work. Many studies have commented on the scope of the problem of disability from low back pain.[1–3] Back pain is a major cause of prolonged disability: 20 to 40 percent of compensation payments are for the back.[4] The costs of caring for neck and low back pain are enormous, and the cost to industry, not only in terms of health care costs but also wage replacement and sickness-and-disability benefits, has been documented repeatedly. The cost of retraining disabled workers is an additional financial burden. There is a "significant increase in cost when permanent partial disability is added, especially in claims involving laminectomies." Indeed, "payments increased dramatically when the injury involves surgery."

Thirty to 33 percent of all costs for occupational injuries are due to back pain, and an average cost for medical expenses of $6,500 *per case* has been documented. The National Safety Council estimated that 400,000 disabling occupational back injuries occurred in 1978, representing 20 percent of all compensable work accidents. Disability from low back pain has been reported as the second major cause of time lost from work.

Many labels have been applied to the group of poorly responsive, chronic pain patients who are refractory to most treatment programs: "pain-prone" personalities,[5] neurotics,[6] and low back "losers."[7] We prefer to call this group Dysfunctional Pain Patients. The outstanding feature of these people is their failure to achieve a functional life (that is, working, retraining, volunteering) before, during, and after treatment.

While pain clinics have become a major source for treatment of this population, no one regimen has been shown to be superior. Part of the problem is lack of a well-defined or consistent data base of the group of patients being treated. Another part of the problem is that outcome criteria and selection processes for treatment vary from clinic to clinic. Most clinics focus on pain relief or modification of behavior and address psychosocial issues and functional outcome only incidentally.[8]

This article discusses the results from a multidisciplinary, intensive program for musculoskeletal pain and disability that has achieved a high rate of success in both pain reduction and improved functional outcome. Preliminary data from an outcome study are presented to assess the efficacy of this model of care.

Return to Work

The major criterion of successful treatment is return to a functional life, and in particular, return to work. While return to work is frequently given as an indication of successful treatment, "studies of vocational adjustment of persons who have entered pain treatment are few."[9] Studies that do exist reveal a low rate of return to work. For patients not working six months to one year, 35 to 55 percent return to the job, but this figure decreases to 10 to 25 percent for those off work a year or more.[10]

Our practice places strong emphasis on return to work for disabled patients. It has been shown that patients who are directed to return to work as part of the treatment program are much more likely to do so than are patients for whom return to work is not an explicit component of the therapy.[11] Return to work is considered by some to be a harsh criterion of success of a pain treatment program.[12] Return to work is clearly an objective that involves imposition of the clinician's values upon the patient. Consequently, in this model, the patient must be willing to accept return to work as a goal if treatment is to be successful.

Pain, as a presenting symptom, is often a manifestation of a musculoskeletal derangement. Pain of musculoskeletal origin is generally benign in nature. This seemingly innocuous assessment of musculoskeletal pain should not, however, lead one to believe that pain is easily treated. Pain treatment is a complicated problem for health providers because it requires exploration of psychosocial and emotional factors simultaneously with the physical findings.

Causes of musculoskeletal pain are trauma, deconditioning, overuse syndromes, muscle imbalance syn-

Frederick J. Balsam MD, Editor

dromes, and referred pain. In addition, there are numerous diagnoses to consider when evaluating most musculoskeletal pain states including: (1) musculoskeletal diseases (for example, degenerative arthritis, discogenic radiculopathy, musculoligamentous strain, myofascial pain, systemic connective tissue disease), (2) vascular diseases, and (3) neurological diseases (for example, peripheral or spinal entrapment syndromes, peripheral neuropathies).

Part of the problem in the treatment of musculoskeletal pain has been the mistaken assumption by the medical community that each of the above-mentioned entities requires an entirely different therapeutic approach. We believe that treatment for pain of each of these relatively common entities is essentially the same: an aggressive, conservative, multidisciplinary management program.

Treatment Program

The treatment program we use involves daily physical therapy, regimen analgesics and nonsteroidal anti-inflammatory drugs (NSAIDS), intensive psychosocial counseling, and extensive patient education to achieve pain relief and to reduce the degree of disability. Selective hospitalization for intensive, conservative, multidisciplinary management to supplement outpatient treatment also may be required. Surgical intervention is performed when necessary, but in our experience, only rarely has been required. Liberal use is made of myofascial injections, spinal mobilization techniques, patient counseling and education, family counseling, and behavior modification.

Effective treatment of musculoskeletal pain disorders must address three issues: relief of pain, adequate education of the patient as to the cause of his or her pain as well as effective coping techniques, and assessment of psychosocial, emotional, and vocational issues. The main goal of the treatment program is to allow patients to return to their premorbid activities. If the patient was part of the work force at the time of injury, then the paramount goal is return to work. Quality of life issues should be addressed also.

Setting treatment goals is essential and must be agreed upon by both patient and health providers. First and foremost, it is necessary to demonstrate to the patient that the pain can be controlled. The patient needs to realize that in many cases, pain can be controlled only by multidisciplinary intervention performed by various professionals working together simultaneously. It would be specious to suggest that any one modality will invariably control a patient's pain.

The cause of dysfunction in the chronic or acute pain patient, in our experience, is a combination of anxiety, poor coping mechanisms, poor problem-solving skills, and an inability to break an ingrained pattern of pain behavior that develops over time. Pain treatment for the dysfunctional patient needs to address these factors.

Time is a crucial factor in treating the DPP. The longer a pain patient remains dysfunctional and out of work, the more difficult it becomes to break the cycle of dysfunction. The longer the patient remains dysfunctional, the more obscure the primary problem becomes. It also becomes more difficult to deal with emotional and psychosocial problems that complicate the patient's presentation. In addition, it must be remembered that some patients, especially those who are out of work due to their pain, may be receiving wage reimbursement. Secondary financial gain provides disincentive to the patient to get well.[13] Therefore, the longer the patient is dysfunctional, the more need there is to approach the case using a broad range of multidisciplinary modalities.

The treatment program must focus on rapid pain relief and rapid restoration of function. For this reason, time contingency planning is used to determine the need for hospitalization. If the patient does not make significant progress within a reasonable time in outpatient care (generally six to eight weeks or less, particularly in those cases where a comprehensive, multidisciplinary, structured, and closely monitored program of management is thought to be necessary), then inpatient treatment is considered.

Selective Hospitalization

Hospitalization of the chronic pain patient must be regarded as one point on a continuum of care. In our view, the hospital is an appropriate environment in which to continue aggressive conservative management of pain patients. We maintain that this is a more preferable approach than is surgery for many patients, in particular, those categorized at high risk for surgical failure.

The current study evaluated 156 consecutive patients admitted to our program in an acute care general hospital for inpatient management of their dysfunctional pain syndrome. All the subjects were failures as outpatients. A review of the results of their treatment reveals the success rates presented in Table 1, next page. The return-to-work rates are relative to how long the patients were out of work before starting treatment.

Analysis of Table 1 indicates that hospitalization played a significant role in returning patients to work, especially patients who were off from work for six or more months. For those patients who were out of work 7 to 12 months, 69 percent returned to work or school. For those out of work 13 to 24 months and 24 months

or more 67 percent and 57 percent respectively returned to work, school, or vocational rehabilitation program.

Following hospitalization, outpatient treatment was continued along with efforts to help the patient maintain a functional life. The frequency of subsequent outpatient visits was determined by the joint assessment of both physician and patient.

Outpatient Pain Treatment Program

The following findings summarize a parallel study examining the return-to-work rates of the outpatient model of treatment, during the years 1980 to 1983. In all, 461 patients were studied. The charts of these patients were pulled at random and included only patients in whom a follow-up contact was made at least six to eight months following discontinuation of active care. Table 2 summarizes the results.

The findings indicate that the treatment program made a significant impact on both acute and chronic pain patients, relative to returning them to a functioning life. The average success rate for this population was 92 percent. As may be expected, success rates varied inversely with length of time out of work. However, the model of treatment was still successful in returning 50 percent of the patients out of work two years or more to the job or to a retraining program. For those out of work one to two years before coming to treatment, 60 percent of the patients were returned to work or school.

Conclusion

Because pain is a complicated phenomenon, treatment programs must be comprehensive enough to deal with the multiplicity of factors operant in DPP. Because pain has both psychological and physical components, medical interventions must deal with both aspects. Failure to do so runs the risk of prolonging disability that otherwise could be reversed or minimized. We maintain that this model of treatment is a cost-effective way to treat the DPP.

The study focused also on the use of selected hospitalization for DPP. Institutionalization at critical points in the treatment program proves effective in curtailing the social and financial costs of outpatient care. The studies performed suggest that with DPP, inpatient care may be more effective than the same program offered on an outpatient basis.

The outcome data should be interpreted in light of two further comments: (1) the difference between the inpatient and outpatient study groups may indicate poorer compliance and poorer ability to control the activities of the outpatient population, as opposed to the inpatient group, (2) unemployment in America during the study years (1980 to 1983) for able-bodied workers was in the range of 8 to 10 percent.

There is need to establish an accurate data base to further define and classify patients who sustain musculoskeletal pain problems and to establish uniform criteria of treatment strategy and outcome criteria.

The Dysfunctional Pain Syndrome should be recognized as being complex in nature, but with comprehensive management, patients suffering from this syndrome can be rehabilitated to more functional lives.

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Table 1. Hospital Patients Returned to Work Related to Time Off from Work Prior to Entering Treatment

Months Out of Work	Total Patients	RTW*	RTS**	RTW + RTS	Percent of Total
0–1	99	93	—	83	94
2–3	14	9	4	13	93
4–6	7	6	—	6	86
7–12	13	5	4	9	69
13–24	9	6	—	6	67
24+	14	6	2	8	57

* Return to work.
** Return to school or vocational rehabilitation program.

Table 2. Outpatients Returned to Work Related to Time Off from Work Prior to Entering Treatment

Months Out of Work	Total Patients	RTW*	RTS*	RTW + RTS	Percent of Total
0–1	353	330	24	346	98
2–3	35	31	1	32	91
4–6	23	18	1	19	83
7–12	20	10	2	12	60
13–24	14	7	2	9	64
24+	16	6	2	8	50

* Return to work.
** Return to school or vocational rehabilitation program.

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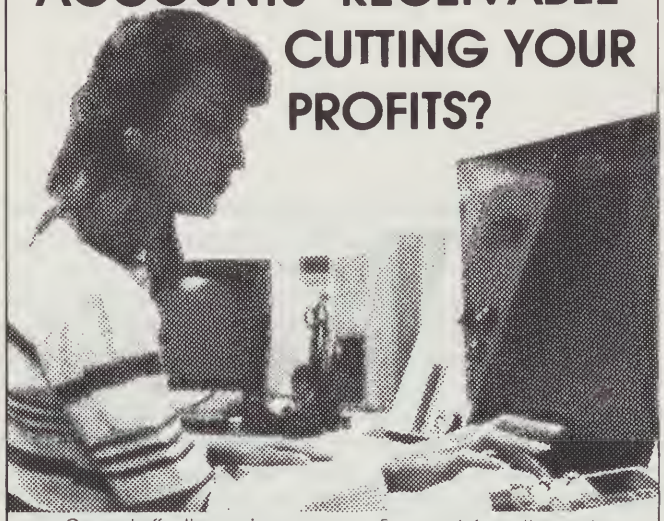
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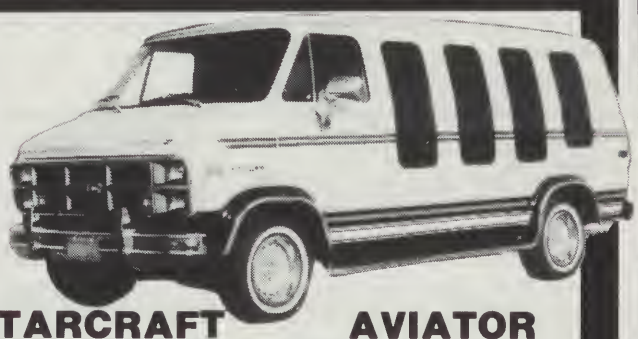
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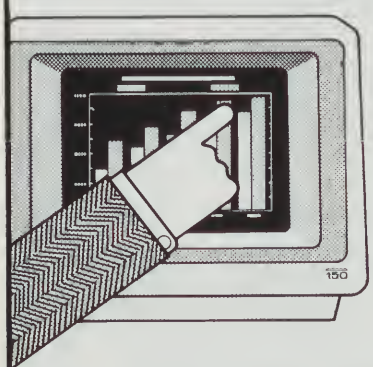
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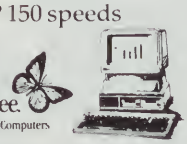
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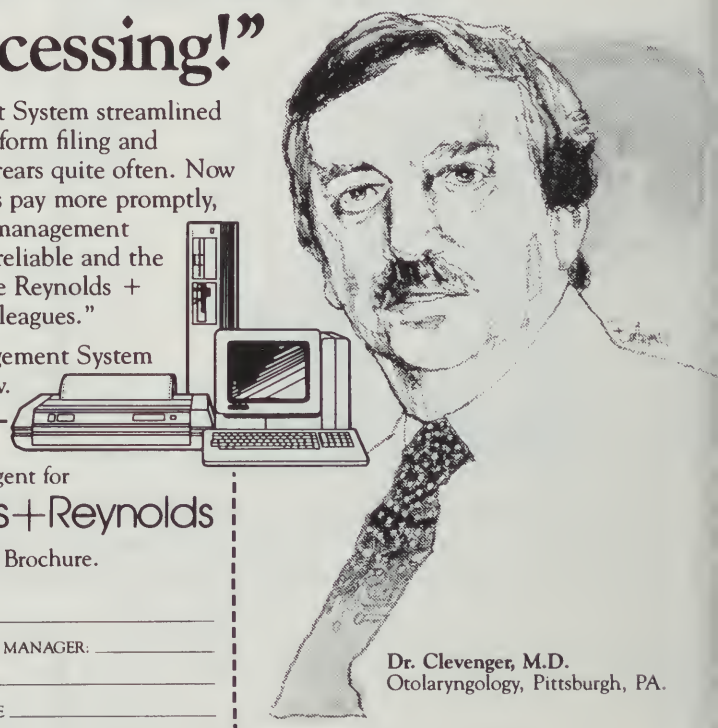
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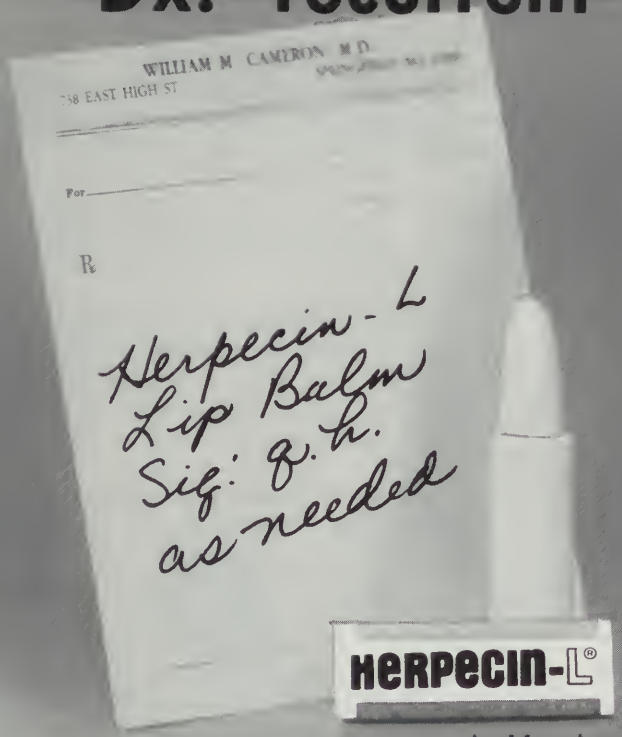


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The Johns Hopkins Medical Institution

All courses at the Turner Auditorium Building unless otherwise indicated. Sponsored Continued Education Activities for 1984–85. Info: Office of Continuing Education, 720 Rutland Ave., Turner Auditorium, Baltimore, MD 21205 (301-955-5880).

Jul 15–19 Control of Biohazards in the Research Laboratory, sponsored by the Department of Safety and Environmental Health, The Johns Hopkins Medical Institutions and the Department of Environmental Health Sciences, The Johns Hopkins University School of Hygiene and Public Health. Info: Dr. Jacqueline Corn, 301-955-2609.

Sep 5–6 Pediatrics for the Practitioner Update, 85, sponsored by the Department of Pediatrics and the Division of General Pediatrics. Fee: $150 physicians, $100 nurse/practitioners, $75 interns. Info: J. Ryan, Program Coordinator.

Sep 20–21 Rheumatology Update, 1985, sponsored by The Johns Hopkins University School of Medicine, The Maryland Society for Rheumatic Diseases, Maryland Lupus Foundation, and The Arthritis Foundation, Maryland Chapter. Fee: $100 physicians, $50 arthritis health professions, $50 nurses; 1 AMA Cat I credit.

Continuously throughout the year. One-week Microsurgery Training Course, Basic techniques and principles, individualized instruction, and practice sessions. Fee: $1,200; 40 AMA Cat I credits. Info: Prog. Coord. (301-955-3169).

The Department of Radiology and Radiological Science offers several courses in abdominal and obstetrical ultrasound: courses scheduled Jan 14 to Dec 6, 1985. Info: Joan Mosmiller, Department of Radiology (301-955-8450).

Basic Practicum—Aug 5–9; Sep 23–27. Fee: $460; 40 AMA Cat I credits.

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June 27–29 Dermatology Days, Ocean City. Early fee: $230; 11.25 AMA Cat I credits.

Sep 17 Current Concepts in Ophthalmology, Baltimore. 6 AMA Cat I credits.

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Miscellaneous

June 27–29 Maryland Chapter of the American College of Emergency Physicians Annual Spring Symposium, Cross Keys Inn, Baltimore. Fees: $220 Maryland ACEP physicians, $250 non-Maryland ACEP, $300 non-ACEP, $75 residents. Info: J. Lewis, The American Registry of Pathology, Armed Forces Institute of Pathology, Washington, DC 20306-6000 (202-576-3285).

Jun 28–29 Training for Health: Prevention and Treatment of Common Athletic Injuries, sponsored by Trieber Associates, Inc. and Southern Medical Association. Fee: $350. Info: Trieber Associates, Inc., 9407 Jodale Road, Randallstown, MD 21133 (301-655-5062).

Jul 26–28 Seventh Annual Pediatrics Primary Care Conference: Pediatrics at the Beach, presented by The Childrens Medical Center/General Pediatrics and the Office of Continuing Medical Education at The Medical College of Virginia. Fee: $275 physician's, $225 physicians-in-training and health care physicians; 13 AMA Cat I credits, 13 PREP credits, 1.3 CEUs. Info: B. Winn, Program Coordinator, CME, Box 48, MCV Station, Richmond, VA 23298 (804-786-0494).

Aug 4–9 An Intensive Review of Internal Medicine, Jefferson Medical College in cooperation with the University of Delaware, 45 Cat I AMA credits. Info: S. Brocka, University of Delaware, 2800 Pennsylvania Ave., Wilmington, DE 19806 (302-573-4400).

Aug 23–24 Training for Health: Prevention and Treatment of Common Athletic Injuries, sponsored by Trieber Associates, Inc. and Southern Medical Association. Fee: $350. Info: Trieber Associates, Inc., 9407 Jodale Road, Randallstown, MD 21133 (301-655-5062).

Oct 4 Selected Topics in Pediatrics, sponsored by Eastern Virginia Medical School, Children's Hospital of the King's Daughters, Norfolk, VA. Info: J. E. Shelton MD, Children's Hospital of the King's Daughters, 800 West Olney Road, Norfolk, VA 23507 (804-628-3798).

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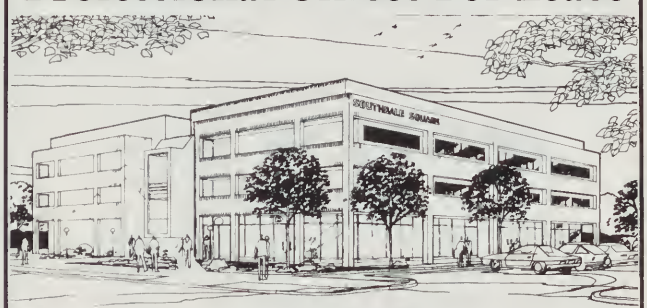
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Business Automation, Inc. 594
Campbell Laboratories 613
The Carousel Hotel 609
Commercial Brokerage Group 615
Consultative Examinations, Inc. 617
Crawford Door Sales of Maryland 610
Curtis 1000 536
Diagnostic Assay Services, Inc. 529
Elcomp Systems Inc. 549
Elkridge Estates 619
Family Home Care 618
John M. T. Finney, III Realtor® 609
Foto Finishers Inc. 597
GMC Truck Center 608
Gordon and Heneson, P.A. 609
Greater Baltimore Medical Center 616
Heron Harbour Isle 543
Hidden Brook Treatment Center 535
The Horizons—Attman Properties 612
Intracare Corp. 550
JBA Leasing 618
Jerry's Toyota 544
King's Grant 526
Knoll Pharmaceutical 560
Koons Porsche Audi 528
Joel R. Kruh Esq. 616
Eli Lilly & Co. 537
Sarah Long 617
Lutheran Hospital 616, 617
Manor Care 578
Marion Laboratories 601
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Maryland Office Systems 610
Med-Chi 556, 608
Medical Mutual Liability . . . . . cover 2, 574
Meridian Healthcare 538
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Sheppard & Enoch Pratt Hosp. 554
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E. R. Squibb 531, 579
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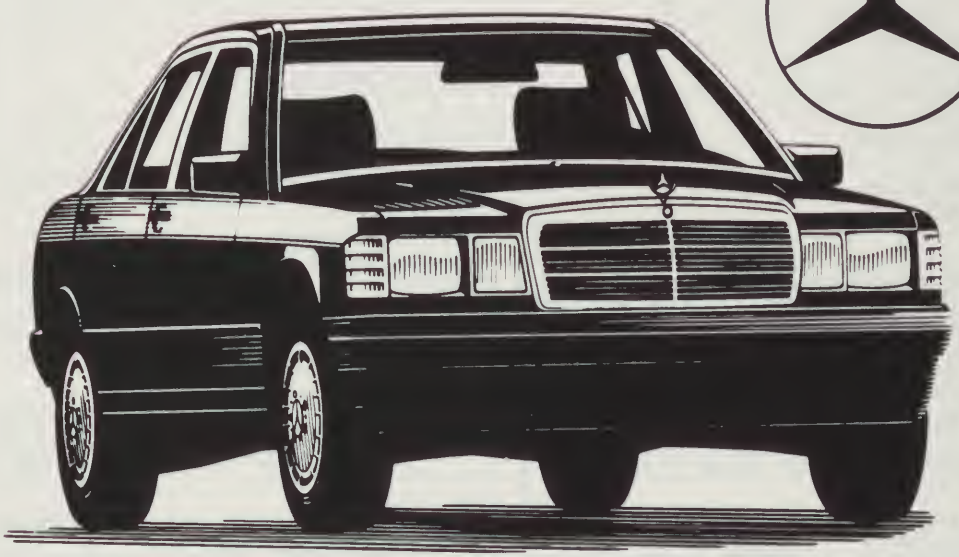
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MISCELLANY

Executive Director's Newsletter 637
Information for Authors 644
Change of Address Form 661
Medical Miscellany 664
Medicolegal Hotline 674
Consultation 692
Members in the News 701
Hotline Numbers 701
Doctors Take Note 708
Physicians' Placement Service 710
Classified Ads 711
Advertisers' Index 713

ARTICLES

Clinical Magnetic Resonance Imaging—John L. Sherman MD, Charles M. Citrin MD, and Bruce J. Bowen MD 679

Osteoarthritis X: Cervical Spondylosis—Carol M. Ziminski MD 683

Atypical Lyme Disease or *Forme Fruste*—Vincent L. Guandolo MD 687

What a Physician Should Know About Ovarian Cancer—Umberto VillaSanta MD 693

DEPARTMENTS

HBP Commentary 640

Maryland Oncology Newsletter 642

Insurance Monitor 647

Semiannual Meeting Announcements 648

Disease Control and Epidemiology Newsletter 651

The Library Page 659

One Minute with Diabetes 662

The Impaired Physician 663

Inside Med-Chi 668

Commentary—Carcinogenic Risk Assessment: Concepts and Issues—M.L. Baeck PhD and Max Eisenberg PhD 672

Discipline Commission Action 703

On the cover: Facade designed by Ellicott and Emmart, Architects, for the Medical and Chirurgical Faculty Library, 1211 Cathedral Street. Rendering accompanied the preliminary drawings and floor plans, May 1908. Article begins on page 668.

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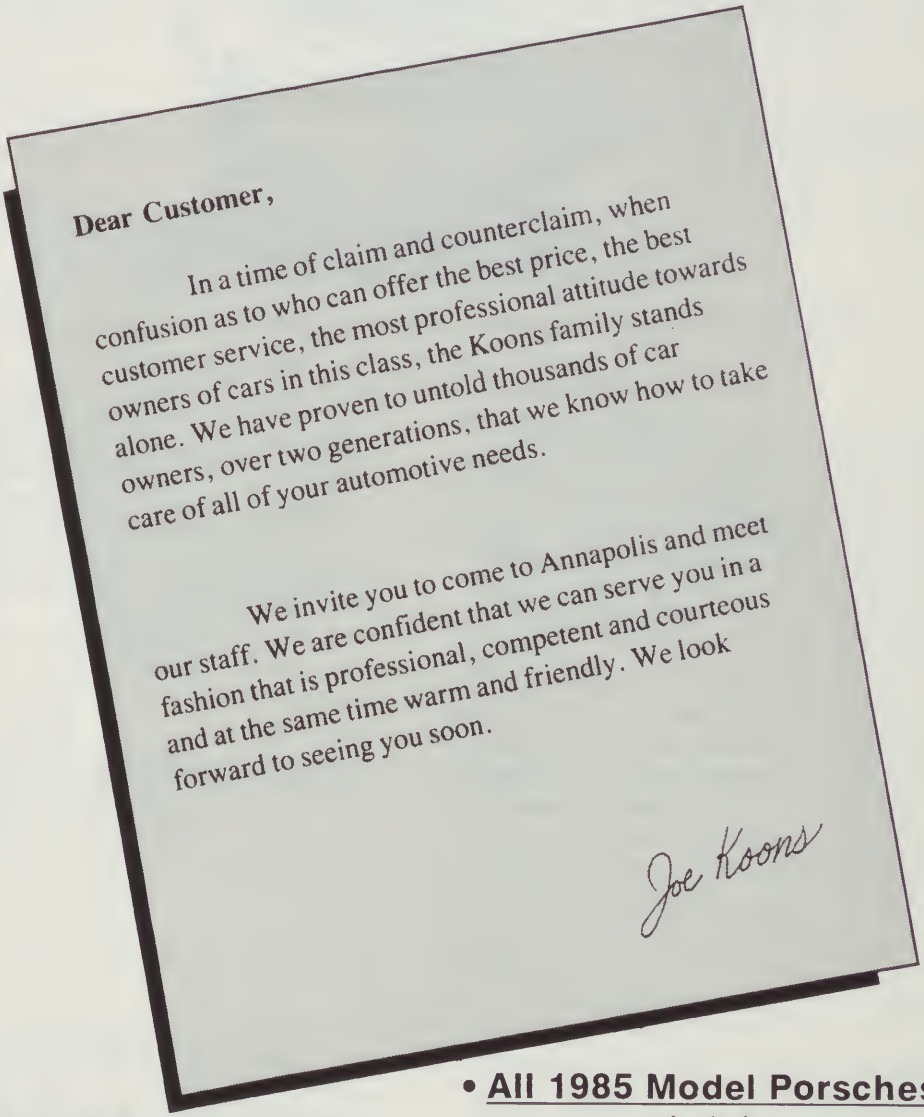
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AN IMPORTANT POINT TO REMEMBER

Many health insurance plans, including Maryland Blue Cross/ Blue Shield, have an exclusion in their policies that reads, "Care for any occupational condition, ailment, or injury arising out of and in the course of employment" is not covered. Maryland Blue Cross/Blue Shield has confirmed that a physician's claim could be denied if the injury or illness falls within the jurisdiction of the physician's Workmen's Compensation Insurance that he is required to carry under Maryland law.

Some physicians have "signed off" their liability to carry Workmen's Compensation Insurance, relying on their health insurance to cover any injuries or illnesses for them and their employees.

All physicians are urged to reevaluate their current coverage. The Med-Chi Agency has a special program for physicians with low group rates and dividend payments. For more information, send in the postcard following this page or call the Med-Chi Agency at 301-539-6642.

ETHICAL OPINIONS

The Faculty's Council recently adopted guidelines concerning conflict of interest of Councilors, Elected Officers, and Committee Chairmen. Any member wishing a copy of these guidelines should contact Eve Lehman at the Faculty Office.

Council also approved a new ethical opinion concerning second opinions:

> The patient has a right to choose his physician unless the patient agrees to limit that choice by contract. When a second opinion is required by an insurance or similar program, both the treating physician and the second physician should explain their respective roles to the patient. The second physician should not actively encourage or induce the patient to change physicians. Should the patient freely choose to transfer his medical care, the second physician may accept the patient if he chooses. The treating physician should honor the patient's choice. Should the second physician disagree with the treating physician's opinion, a third opinion should be suggested. Whatever the outcome, the second physician should strive to communicate with the treating physician.

If you have any questions concerning this opinion, contact Louis C. Breschi, MD, Chairman of the Committee on Professional Ethics, or Judith Wood, Faculty Legal Counsel.

John Sargeant

Executive Director

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Executive Director's Newsletter

July 1985

LIABILITY INSURANCE INCREASES

A number of physicians have indicated their intention to discontinue the practice of medicine because the escalating cost of professional liability insurance makes it impossible to continue. It would be extremely helpful in our future legislative efforts to have documentation of these incidents. If you or someone you know has left practice or is planning to do so, please contact me at the Faculty office, 301-539-0872 or 800-492-1056. Let me know your specialty, number of years in practice, location of practice by county, amount of professional liability premium - current billing and amount of premium for immediate past year.

BREAST CANCER PAMPHLET

"What You Are About to Read on Breast Cancer Could Save a Life...Yours!" is the title of a new brochure on breast cancer. It was written by Faculty members who are specialists in the diagnosis and treatment of breast disease. It is especially for physicians to use with their patients in explaining the management choices available. It will help patients to participate fully in the decision-making process. The pamphlet is a joint effort with members of the Maryland General Assembly. THE PAMPHLET IS FREE IN UNLIMITED QUANTITIES. To order, call the Faculty office and ask for Diane Sakwa.

RESIGNATION FROM MEDICARE PROGRAM

Physicians who no longer wish to participate in the Medicare program must submit their resignation in writing by October 1, 1985. Letters may be submitted immediately; however, resignation will not be effective until October 1, 1985.

PROFICIENCY TESTING

By now, most physicians in Maryland are aware that the Division of Laboratory Licensure, Certification and Training has instituted a proficiency testing program for physicians who perform in-house tests. The list of exempted test procedures also has been circulated. You should be aware that if no proficiency test exists for a particular test procedure, you are not required to undergo proficiency testing for that procedure. For more information, call the Division at 301-225-6100.

SEMIANNUAL MEETING RESOLUTIONS

Resolutions to be considered by the House of Delegates at its Semiannual Session on Saturday, September 28, 1985 must be received in the Faculty office by

FRIDAY, AUGUST 2, 1985

Resolutions must be sponsored by a member or component society of the Faculty, the Council, or committees of the Faculty. A resolution introduced by an individual member must have the endorsement of either one-third of the membership of his component society or 30 members of his component society, whichever is smaller.



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HBP Commentary

Historical Notes: Early Measurement of Blood Pressure

CAROL LEWIS

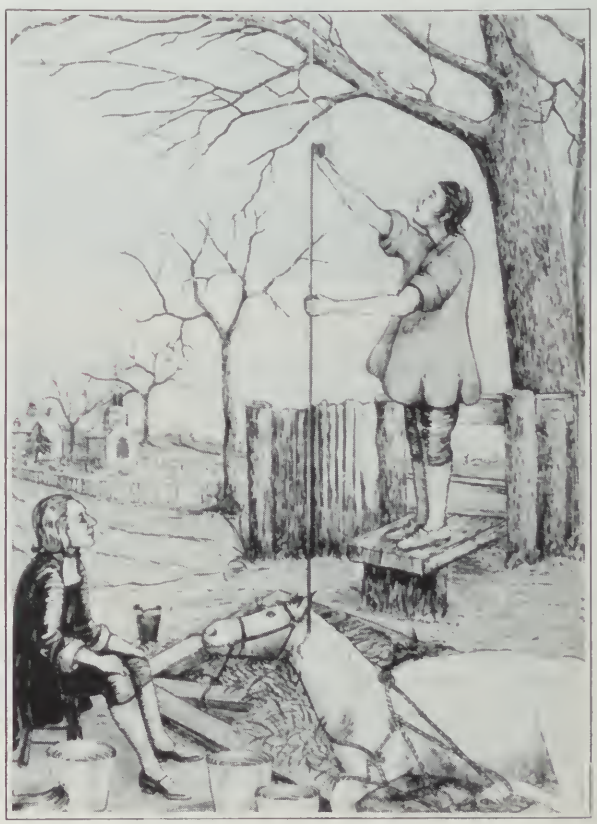
The standard method of the indirect measurement of blood pressure is based on the principle of arterial occlusion and blood pressure detection by various techniques, the first of which was palpation, described by Scipione Riva-Rocci in 1896.[1] The technique has changed little over the years, but recommendations for its standardization have been published and revised regularly by the American Heart Association since 1939, and reviews of the subject have attempted to identify the shortcomings of the technique so as to improve accuracy. A recent and delightful book, *Exploring The Heart*, by Julius H. Comroe MD, describes the history of blood pressure measurement.[2]

Until the early 1700s, no one had ever measured arterial blood pressure, in man or in any other animal. For centuries physicians felt the patient's pulse at the wrist and labeled it hard or soft but had no means of evaluating anything but gross changes. About 1707 an English clergyman, Stephen Hales, was the first to make precise measurements of blood pressure on a variety of animals with the help of a friend, William Stukeley, while both were at Cambridge. Hales was a divinity student and Stukeley was a medical student. In 1709 Hales became curate in the parish of Teddington and lived there for the rest of his eighty-three years, and in this quiet parish on the Thames (now a residential section southwest of London), he continued by himself to make his remarkable measurements.

Hales was not a physician, and he was not especially interested in medicine or in the heart or circulation. He was interested in what governs the flow of fluids, in particular, what makes sap rise from the bottom to the top of a tree. While pondering on sap and trees, he decided to measure the rise of sap in animals, that is the vertical height to which the heart could pump arterial blood. In a typical experiment, he tied a brass tube into a main artery of an animal, usually a horse, and connected the other end of the brass tube to a long glass tube, using the flexible windpipe of a goose as the connector. He then held the glass tube vertically and allowed arterial blood to rise in it. For a pressure of 200 × 13.6 (the specific gravity of mercury) or 2,720 millimeters, he needed a tube about 9 feet long.

With this tube Hales learned how high the blood went up the tube; he saw it bounce up and down with systole and diastole, and he saw the effects of deep breathing, struggling, and discomfort. He also removed, ounce by ounce, 17 quarts of blood and saw the horse's blood pressure fall from 8 feet 3 inches to 2 feet 4 inches high. He measured the pressure in the great veins and in the pulmonary artery, the volume of the cavities of the left and right ventricles, and the volume and velocity of blood ejected from the heart during each beat.

But Hales really wanted to measure the rise of sap in plants. In 1720, quite by accident, he cut off a stem of a vine too near its "bleeding" time. He bandaged it by tying a piece of bladder tightly over the cut stem, but he found that instead of stopping the oozing, the bladder became more and more tightly distended. From this he knew that he could get actual numbers by attaching his long glass tubes, designed to measure blood pressure, to the cut stems and measuring how high the sap rose in them. He then went on to determine the factors controlling the flow of sap, including transpiration and root pressure. Because sap rose very much higher in tall plants and vines than blood did in a tube in an animal's artery, Hales had to devise mercury-filled U-tubes to measure sap pressure. Thus the eighteenth century clergyman made two great scientific discoveries: one of the fundamental importance to botany and the other to physiology and medicine. Hales published a description of his mercury manometer in *Vegetable*



HBP Commentary is contributed by the Maryland High Blood Pressure Commission, 201 W. Preston St., Baltimore, MD 21201 (301-225-5891). Editors: R. Patterson Russell MD, Past Chairman; Donald O. Fedder PharmBS, DrPH, Chairman; and Carol Lewis MPH, ScD, Executive Director.

Staticks in 1727.[3]

About a hundred years had elapsed between Harvey's discovery of the circulation of the blood and Hales's work on measurement of arterial blood pressure. Another hundred years passed before the latter was widely adopted in physiological laboratories throughout Europe and England. While Harvey's discovery had met with bitter opposition for forty or fifty years, Hales's work apparently met with no opposition. It simply was not put to use.

In 1828 a French medical student, Jean Leonard Marie Poiseuille, popularized the use of the mercury manometer and U-tube. He was not interested in hypertension, but he wanted to know where the resistance to blood flow was in the circulation of animals and, especially, whether there was really a considerable resistance to flow through a normal aorta from its beginning at the left ventricle to its end in the lower abdomen. All good physiologists in 1825 claimed that there was; Poiseuille thought otherwise. To prove his view, he needed good instruments to measure blood pressure. If the aorta offered resistance to blood flow, blood pressure should decrease along the aorta. Whether he "invented" or rediscovered it, he used mercury in a U-tube, and calculated that he could reduce the tube length to 1/13.6 of 9 feet and have a manageable, 8-inch, portable instrument. His U-tube mercury manometer was used to measure blood pressure for the next 100 years in every student laboratory in Europe and America.

Poiseuille found blood pressure to be almost identical at the beginning and at the end of the aorta in a supine animal, and showed that there was no measurable resistance in the aorta. This meant that normally the main resistance to arterial blood flow had to be in the small arterioles, which was a key finding in the later development of treatment of high blood pressure. Poiseuille went on to formulate a law governing the resistance to flow of liquids through such small vessels.

In 1847 a German physiologist, Carl Ludwig, then professor of comparative anatomy at the University of Marburg, put a float on top of Poiseuille's mercury column and added a horizontal scribe that recorded blood pressure continuously. In this way he obtained continuous curves: the variations in height measured ups and downs in blood pressure, and the horizontal distance measured time. This enabled Ludwig to record on paper and then analyze carefully, and at length, continuous tracings of systolic and diastolic blood pressure and heart rate, instead of depending on visual memory of rapidly changing pressures and heart rate. It also provided permanent records of changes in blood pressure that occurred when he stimulated nerves or injected drugs into the circulation to study factors that regulate heart rate and blood pressure.

Like Hales, Ludwig's contributions to medical science were many. In 1865 he became professor of physiology at the University of Leipsig and director of its new Physiological Institute. There he collected a group of brilliant students who, with Ludwig, formulated the first concept of how the kidney separates urine from blood flowing through that organ, learned the location of nerve centers in the brain stem that regulate heart rate and blood pressure, devised an instrument to measure blood flow to organs, perfused isolated organs with defibrinated blood, and discovered sensory nerve endings in the beginning of the aorta that regulated the level of aterial blood pressure.

As cardiovascular physiologists became more sophisticated Poiseuille's mercury manometer became an unsatisfactory instrument for research, though it has remained the standard against which all new manometers must be tested for accuracy. The problem with using mercury for research on blood pressure was that a column of mercury has mass and inertia and therefore cannot move quickly enough to record the true systolic peak and true diastolic trough of blood pressure, data needed to measure the dynamics of cardiac contraction. Scores of new manometers were devised in the nineteenth century for direct measurement in animals and even a few for use in humans, all requiring insertion into an artery. Some of those for humans were simply impractical, some gave inconsistent numbers, some yielded very consistent numbers that were incorrect, and some were pretty good instruments—not unlike the situation today. None could be used routinely or repeatedly on patients in a physician's office to follow the course of blood pressure or the effects of treatment.

(Conclusion of this two-part article will appear in the September *MMJ*.)

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1. O'Brien, E.; Fitzgerald, D.; and O'Malley, K. "Blood Pressure Measurement: Current Practice and Future Trends." *Br Med J* 1985: 729–34.

2. Comroe, J. H. *Exploring the Heart: Discoveries in High Blood Pressure and Heart Disease.* New York: W. Norton & Sons, 1984: 218–24.

3. Hales S. *Vegetable Staticks.* London: W & J Innys and T Woodward, 1727.

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It is extremely important that all young females be taught breast self-exam. The ideal time to do it is one week after the menstrual period, when there is no breast engorgment. After age 35, a woman may have mammography done every two or three years. However, mammographic examinations may be initiated earlier in high-risk groups such as those with family history of breast cancer.

Not all breast masses are cancerous. It is estimated that cancer of the female breast constitutes 20 percent of all breast masses. The most common tumor found in teenagers and women in their early twenties is the *fibroadenoma*. This is a benign, firm tumor usually measuring about 2 cm that is not painful, is freely mobile within the breast, and is not adherent to skin or underlying fascia. Complete local excision is the recommended treatment, as it may grow to a giant fibroadenoma and destroy the breast.

Fibroadenomas have no relation to *cystosarcoma phylloides*, a malignant condition of the breast that tends to occur in adults, has a knobby surface, and invades the surrounding tissues. While small lesions can be treated by wedge resection (with free margins), large lesions may require simple mastectomy. Cystosarcoma phylloides rarely metastasizes, and if it does, it is via blood to lungs and other organs. Therefore, there is no need for axillary dissection.

The most common mass in the breast is due to *fibrocystic disease*. Such masses are cystic and can be tender from distention. These can be managed by aspiration. If so treated, three things must be observed:

1. Color of the aspirate: yellow to green indicates fibrocystic disease. There is no need to send this aspirate for cytology as it usually contains degenerated cells that can be confused with malignancy.
2. Mass has to completely disappear after aspiration.
3. Patient must be re-examined in two to four weeks to insure that the cyst did not recur.

Bloody aspirate, persistant mass after aspiration, or recurrent cyst or mass two to four weeks later are indications for surgical excision as other tumors cannot be ruled out. This is indicated even if mammography is negative.

Other masses encountered in the breast are due to *sclerosing adenosis*. These firm and usually tender masses are formed mostly of fibrous tissue and, to a lesser extent, of multiple small cysts. Their most common locations are in the upper outer quadrants of both breasts. Sclerosing adenosis may contain massive fibrosis, which on mammography is referred to as *dysplasia*. Severe dysplasia may interfer with the detailed visualization of breast parenchyma and make it impossible for the radiologist to interpret findings. Sclerosing adenosis causes moderate to severe pain and tenderness just prior to and during the early menstrual period. The pain may subside or even disappear after the menstrual period; occasionally the pain persists. The cause of sclerosing adenosis is unknown; however, it may be due to hormonal imbalance. Persistent severe pain can be managed by daily low doses of premarin for three months. Surgical excision does not relieve the symptoms but confirms the diagnosis.

Other tender masses occurring in female breasts are *acute* and *chronic mastitis*. These usually are seen in women of child-bearing age. Acute mastitis should be incised and drained as soon as possible, and the patient placed on systemic antibiotics. Chronic mastitis should be excised and the area closed over a drain. Because *inflammatory carcinoma* usually presents as an inflamed breast, it is advisable to submit a small piece of skin, subcutaneous tissue, and breast tissue for pathological examination.

Other rare masses include *Mondor's disease*, a thrombosis of one of the superficial veins of the breast. It is a self-limiting disease, and cold compresses are used to control the discomfort. *Giant hypertrophy* of the breast is a benign condition usually seen in early pregnancy. It is characterized by rapid enlargement of both breasts with pain. Therapeutic abortion may be indicated if there is danger of pressure necrosis of skin and nipple.

Patients may present with *nipple discharge*. The breast should be examined and mammographed. The presence of a mass in the breast takes priority over the discharge. Secretions from the nipple can be yellow to green indicating fibrocystic disease in which the cyst drained into a main duct. Bloody discharge can be due to benign conditions such as intraductal papilloma or hemorrhage in fibrocystic disease. However, intraductal carcinoma or intracystic carcinoma also may produce bloody discharge. Therefore, the bleeding duct and its lobule should be excised.

In general, breast masses can be detected by clinical examination about 80 percent of the time. However, routine mammography may reveal a small, suspicious nodule deep in the breast that cannot be detected clinically. These masses can be approached either by wedge resection or preferably by needle localization of the nodule or mass. In needle localization, ¼ to ½ ml methylene blue is injected into the mass under mammography observation. Blue tissues are then removed while the patient is under general anesthesia. In either case, the tissues are re-x-rayed to insure that the mass is within the tissues removed. The patient should have

If you have questions, please call or write The Surgical Oncology Program at the University of Maryland Medical System, Room N13E02, Baltimore, MD 21201 (301-528-5224).

another mammogram a few weeks later to be sure that the entire suspicious shadow had been removed.

Tumor Conference is held weekly on Fridays between 8 and 9 AM in Room N13E28. This is an open meeting; any physician is welcome to attend. Physicians may present cases, but please call before Friday to schedule your case, and bring the pathological slides with you.

E. GEORGE ELIAS MD
University of Maryland, Surgical Oncology Program

Future Med-Chi Meetings

1985 Semiannual
September 1–8
Bermuda

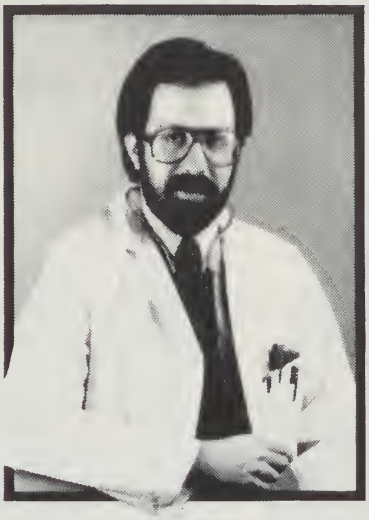
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Montreal

September 14–17
Post-Convention Trip
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Information for Authors

Med-Chi members reading papers before organizations are invited to submit their papers to the MMJ for consideration for publication.

The *Maryland Medical Journal* is the monthly publication of the Medical and Chirurgical Faculty of the State of Maryland. Its goals are educational and informative: the publishing of scientific articles and other technical information as well as editorials, special articles (evaluations, position papers, reviews of nonscientific subjects), membership news, notices of medical events, legislative and governmental news, meetings, continuing education courses, and programs and policies of the Faculty.

Manuscripts may be sent to Editor *MMJ*, 1211 Cathedral St., Baltimore, MD 21201. Articles are accepted for publication on the condition that they are contributed solely to this journal. Transmittal letters should designate one author as correspondent and include his/her address and telephone number. Manuscripts are reviewed by the editor, editorial board members, and guest reviewers. The final decision is reserved for the Editor.

Specifications

Manuscripts must be original typed copy, double-spaced throughout (including text, case reports, legends, tables, and references) with margins of at least one inch. Number pages consecutively. Please submit two additional copies.

Include in the manuscript the concise title, full name of the author (or authors) with highest degree, academic and professional titles, affiliations, and any institutional or other credits.

An introductory synopsis/abstract of approximately 100–150 words is required.

Tables are to be typed on separate sheets of paper, numbered, and have a brief descriptive title. The Editor reserves the right to edit tables. Be sure that statistics are consistent in both tables and text.

References are limited to those citations noted in the text. References are to be typed double-spaced and numbered consecutively as they appear in text. They will be examined critically at the time of review and must be kept to a minimum. Personal communciations and unpublished data should not be included. The following are necessary: names of all authors, complete title of article cited (lower case), name of journal abbreviated according to *Index Medicus*, volume number, first and last page numbers, and year of publication. For more extensive information about preparing medical articles for publication, the editors suggest the International Committee of Medical Journal Editors: Uniform requirements for manuscripts submitted to biomedical journals. The complete document is available in the June 1982 issue of the *Annals of Internal Medicine*.

Illustrations are material that cannot be set in type. Photographic material must be submitted as high-contrast, glossy prints. Drawings and graphs must be done professionally in india ink on high-grade white drawing paper. *Omit illustrations that do not increase understanding of text, and limit them to a reasonable number.* Four or fewer illustrations should be adequate for a manuscript of 4 to 5 typed pages. Legends are to be typed on a separate sheet of paper. Type on a gummed label and affix to the back of each illustration: figure number, title of manuscript, name of senior author, and arrow indicating top. Legends for illustrations should be typed on a separate page with numbers corresponding to those on the photographs and drawings. *Cost of printing color photographs must be borne by the author.*

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Manuscripts are subject to editorial modification and such revisions necessary to being them into conformity with *Journal* style.

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See following page for brief summary of prescribing information.

SORBITRATE®
(ISOSORBIDE DINITRATE)

Please consult full prescribing information before use. A summary follows:

INDICATIONS AND USAGE: SORBITRATE (isosorbide dinitrate) is indicated for the treatment and prevention of angina pectoris. All dosage forms of isosorbide dinitrate may be used prophylactically to decrease frequency and severity of anginal attacks and can be expected to decrease the need for sublingual nitroglycerin.

The sublingual and chewable forms of the drug are indicated for acute prophylaxis of angina pectoris when taken a few minutes before situations likely to provoke anginal attacks. Because of a slower onset of effect, the oral forms of isosorbide dinitrate are not indicated for acute prophylaxis.

CONTRAINDICATIONS: SORBITRATE is contraindicated in patients who have shown purported hypersensitivity or idiosyncrasy to it or other nitrates or nitrites. Epinephrine and related compounds are ineffective in reversing the severe hypotensive events associated with overdose and are contraindicated in this situation.

WARNINGS: The benefits of SORBITRATE during the early days of an acute myocardial infarction have not been established. If one elects to use organic nitrates in early infarction, hemodynamic monitoring and frequent clinical assessment should be used because of the potential deleterious effects of hypotension.

PRECAUTIONS: General: Severe hypotensive response, particularly with upright posture, may occur with even small doses of SORBITRATE. The drug should therefore be used with caution in subjects who may have blood volume depletion from diuretic therapy or in subjects who have low systolic blood pressure (eg, below 90 mmHg). Paradoxical bradycardia and increased angina pectoris may accompany nitrate-induced hypotension. Nitrate therapy may aggravate the angina caused by hypertrophic cardiomyopathy.

Marked symptomatic, orthostatic hypotension has been reported when calcium channel blockers and organic nitrates were used in combination. Dose adjustment of either class of agents may be necessary.

Tolerance to this drug and cross-tolerance to other nitrates and nitrites may occur. Tolerance to the vascular and antianginal effects of isosorbide dinitrate or nitroglycerin has been demonstrated in clinical trials, experience through occupational exposure, and in isolated tissue experiments in the laboratory. The importance of tolerance to the appropriate use of isosorbide dinitrate in the management of patients with angina pectoris has not been determined. However, one clinical trial using treadmill exercise tolerance (as an end point) found an 8-hour duration of action of oral isosorbide dinitrate following the first dose (after a 2-week placebo washout) and only a 2-hour duration of effect of the same dose after 1 week of repetitive dosing at conventional dosing intervals. On the other hand, several trials have been able to differentiate isosorbide dinitrate from placebo after 4 weeks of therapy and, in open trials, an effect seems detectable for as long as several months.

Tolerance clearly occurs in industrial workers continuously exposed to nitroglycerin. Moreover, physical dependence also occurs since chest pain, acute myocardial infarction, and even sudden death have occurred during temporary withdrawal of nitroglycerin from the workers. In clinical trials in angina patients, there are reports of anginal attacks being more easily provoked and of rebound in the hemodynamic effects soon after nitrate withdrawal. The relative importance of these observations to the routine, clinical use of isosorbide dinitrate is not known. However, it seems prudent to gradually withdraw patients from isosorbide dinitrate when the therapy is being terminated, rather than stopping the drug abruptly.

Information for Patients: Headache may occur during initial therapy with SORBITRATE. Headache is usually relieved by the use of standard headache remedies or by lowering the dose and tends to disappear after the first week or two of use.

Drug Interactions: Alcohol may enhance any marked sensitivity to the hypotensive effect of nitrates.

Isosorbide dinitrate acts directly on vascular smooth muscle, therefore, any other agent that depends on vascular smooth muscle as the final common path can be expected to have decreased or increased effect depending on the agent.

Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term studies in animals have been performed to evaluate the carcinogenic potential of this drug. A modified two-litter reproduction study in rats fed isosorbide dinitrate at 25 or 100 mg/kg/day did not reveal any effects on fertility or gestation or any remarkable gross pathology in any parent or offspring fed isosorbide dinitrate as compared with rats fed a basal-controlled diet.

Pregnancy Category C: Isosorbide dinitrate has been shown to cause a dose-related increase in embryotoxicity (increase in mummified pups) in rabbits at oral doses 35 and 150 times the maximum recommended human daily dose. There are no adequate and well-controlled studies in pregnant women. SORBITRATE should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when SORBITRATE is administered to a nursing woman.

Pediatric Use: The safety and effectiveness of SORBITRATE in children has not been established.

ADVERSE REACTIONS: Adverse reactions, particularly headache and hypotension, are dose-related. In clinical trials at various doses, the following have been observed.

Headache is the most common (reported incidence varies widely, apparently being dose-related, with an average occurrence of about 25%) adverse reaction and may be severe and persistent. Cutaneous vasodilation with flushing may occur. Transient episodes of dizziness and weakness, as well as other signs of cerebral ischemia associated with postural hypotension, may occasionally develop (the incidence of reported symptomatic hypotension ranges from 2% to 36%). An occasional individual will exhibit marked sensitivity to the hypotensive effects of nitrates and severe responses (nausea, vomiting, weakness, restlessness, pallor, perspiration, and collapse) may occur even with the usual therapeutic dose. Drug rash and/or exfoliative dermatitis may occasionally occur. Nausea and vomiting appear to be uncommon. Case reports of clinically significant methemoglobinemia are rare at conventional doses of organic nitrates. The formation of methemoglobin is dose-related and, in the case of genetic abnormalities of hemoglobin that favor methemoglobin formation, even conventional doses of organic nitrate could produce harmful concentrations of methemoglobin.

DOSAGE AND ADMINISTRATION: For the treatment of angina pectoris, the usual starting dose for sublingual SORBITRATE is 2.5 to 5 mg; for chewable tablets, 5 mg; for oral (swallowed) tablets, 5 to 20 mg; and for controlled-release forms, 40 mg.

SORBITRATE should be titrated upward until angina is relieved or side effects limit the dose. In ambulatory patients, the magnitude of the incremental dose increase should be guided by measurements of standing blood pressure.

The initial dosage of sublingual or chewable SORBITRATE for prophylactic therapy in angina pectoris patients is generally 5 or 10 mg every 2 to 3 hours. Adequate controlled clinical studies demonstrating the effectiveness of chronic maintenance therapy with these dosage forms have not been reported.

SORBITRATE in oral doses of 10 to 40 mg given every 6 hours or in oral controlled-release doses of 40 to 80 mg given every 8 to 12 hours is generally recommended. The extent to which development of tolerance should modify the dosage program has not been defined. *The oral controlled-release forms of isosorbide dinitrate should not be chewed.*

DOSAGE FORMS AVAILABLE: Sublingual Tablets (2.5, 5, 10 mg); Chewable Tablets (5, 10 mg); Oral Tablets (5, 10, 20, 30, 40 mg); Sustained Action Tablets (40 mg).

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Insurance Monitor

Ophthalmology

The American Academy of Ophthalmology has announced a professional liability insurance program for Fellows or Members of the Academy. The program has been developed with INAPRO, the professional liability manager for the CIGNA Property and Casualty Group. The program includes a choice of claims-made or occurrence coverage and three separate risk classifications for medical practice, minor surgery, and major surgery. For further information, contact your broker or Glenn Nyhan & Associates, the program administrators, at 1-800-228-5311 in California.

• • •

American College of Obstetricians and Gynecology

A spokesman for INAPRO confirmed plans for changes in the program. Effective April 1, 1985, no new policies will be written for OB/GYNs, and renewal policies will be restricted to coverage limits of $500,000/$1,000,000. The INAPRO spokesman noted the possibility that renewals may not be accepted beyond six months.

• • •

PHICO Group

In August 1984 the Pennsylvania Casualty Company announced that occurrence policies would no longer be offered or renewed and that coverage would be declined for OB/GYNs with prior claims. In addition, no coverage would be provided to self-standing independent physicians after November 1, 1984. Organized physician groups of five or more physician members subject to a Risk Management program will be considered for coverage.

• • •

Anesthesiology

The January 1985 issue of *Claims Rx*, a publication of the physician-owned NORCAL Mutual Insurance Company (California) contained a strong warning: physician policyholders who administer anesthesia will not be protected by their NORCAL policy if they leave the operating room without suitable replacement (another *physician* trained in anesthesiology).

• • •

St. Paul Results

In a February 7, 1985 letter to shareholders, Robert J. Haugh, Chairman and chief Executive Officer of The St. Paul Companies, Inc., and Subsidiaries, announced a year-end operating loss from continuing operations of $196.8 million, or $9.82 per share. Fourth quarter losses from continuing operations were $103.6 million, or $5.17 per share.

Haugh's report noted severe underwriting losses, particularly in the commercial lines of St. Paul's property-liability insurance operations, as the "result of widespread, intense price competition over the last few years."

Pointing to corrective price increases and underwriting actions, Haugh predicted that "1985 will be a year of recovery for The St. Paul Companies."

The St. Paul Companies includes St. Paul Fire and Marine Insurance Company, the largest medical malpractice insurer in the U.S.

• • •

Round Two?

The "Crisis of Affordability" may have arrived in several states.

According to the American Medical Association, 20 malpractice claims were filed per 100 physicians in 1983, compared with five per 100 physicians in 1975. Jury Verdict Research, a national monitor, examined 171 malpractice verdicts in 1984. The average award was $955,000, more than three times the average award in 1975.

The AMA Task Force on malpractice reports on significant rate increases around the country and notes the following:

- An Indiana carrier announced an average 60 percent increase effective October 1, 1984
- A North Carolina company recently announced a 50 percent increase
- In Utah, a professional liability insurer announced a 42 percent increase
- NORCAL, a California physician-owned company, announced a 27 percent rate increase effective January 1, 1985
- In December 1984 a New Jersey company reported a 24 percent increase
- New York State approved a 52 percent rate increase

On December 31, 1984, Shand, Morahan & Company, Inc. announced that it would no longer write new medical malpractice coverage for physicians, surgeons, dentists, hospitals, or miscellaneous medical professionals in Florida. Renewal policies will be offered, although some restrictions in coverage may apply.

For more information or answers to your insurance questions, contact your insurance representative.

WHAT DO YOU THINK OF THE JOURNAL?
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For latest information on Med-Chi Annual and Semiannual Meetings, read the **Journal** every month.

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Farewell cocktail reception

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Send to:

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of the State of Maryland
1211 Cathedral Street
Baltimore, Maryland 21201

$300 Physician Registration Fee
Plus travel cost listed below

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_____ Non-Smoking

I would like to make reservations for the MED-CHI Semiannual Meeting to be held in Bermuda, September 1 to 8, 1985. Enclosed is a deposit of $ _____ ($200 per person) payable to the Medical and Chirurgical Faculty of the State of Maryland for _____reservations in the following accommodations:

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( ) Triple occupancy @ $1029 per person + $3 departure tax
( ) Quad occupancy @ $ 979 per person + $3 departure tax
( ) Single occupancy @ $1709 per person + $3 departure tax
( ) Children under 12, sharing room with two adults
@ $519 per child + $3 departure tax

Deposits and monies are refundable (Less a $25 administrative fee as NOTED UNDER PARAGRAPH 7 IN THE TOUR PARTICIPANTS CONTRACT). CANCELLATION MUST BE RECEIVED AT MED-CHI BY JUNE 24, 1985. AFTER THIS DATE, REFUNDS WILL ONLY BY GIVEN IF THE RESERVATION IS RESOLD.

_____ Also enclosed is a check for $300 for Physician Registration Fee.

I have read the attached Tour Participant's Contract and accept its provision.

Signature	Date	Component Society
Name	Address	
City, State, Zip	Office Phone	Home Phone

Please list clearly the first and last names of all participants/and ages of any children accompanying you on the trip:

_____ _____

_____ _____

RESPONSIBILITY: The Medical and Chirurgical Faculty of Maryland ASSUMES NO LIABILITY FOR, AND THE PASSENGER AGREES THAT MEDICAL AND CHIRURGICAL FACULTY OF MARYLAND SHALL NOT BE RESPONSIBLE FOR OR LIABLE FOR, AND WAIVES ANY CLAIMS AGAINST MEDICAL AND CHIRURGICAL FACULTY ARISING OUT OF (a) loss, expense, damage, accident, delay, inconvenience, irregularity, injury, or death which results from, or is occasioned by, directly or indirectly, any defect or the acts or failures to act, whether negligent or otherwise, of any such airline, other transportation company, rental car company, hotel, restaurant, or other travel supplier engaged in conveying the passenger or otherwise carrying out the arrangement included in your MED-CHI trip or related connecting flights, including but not limited to delays, schedule changes, or flight cancellations by the airline, overbooking by the airline or hotel, or strikes affecting the airline or hotel, or (b) any other cause or factor, of whatsoever nature, beyond MED-CHI's control. MED-CHI reserves the right to decline, to accept, or retain any person as a member of the air tour or to change or withdraw such tour at any time as circumstances warrant. Any deviation from such tour which the passenger indicates is solely the responsibility of the passenger.

One Size Fits All

But not when it comes to chronic schizophrenia. Victims of this devastating disorder have special needs requiring special attention. What works for one patient doesn't always work for another.

With this in mind, Sheppard Pratt Hospital introduced a new, comprehensive program on July 1, based on social learning theory. This program joins our traditional Psychotherapy approach, providing *two options* for treatment of schizophrenic patients.

Each program places a strong emphasis on *intensive, individualized* treatment of the patient. That personalized attention begins with a careful physical and psychological evaluation which is continually updated throughout the patient's stay. Based on these assessments, patients receive treatment tailored to their specific needs. For some, the milieu therapy approach based on psychodynamic principles is best. For others, the social learning theory approach is more effective.

Patients in both programs have their own personal psychotherapists, and are placed in a structured, consistent environment that is designed to reduce their internal chaos. Medications are not used as substitutes for social or psychological needs, but are parts of a comprehensive treatment program.

Our staff of nurses, mental health workers, activity therapists, social workers, psychologists and psychiatrists work together with the patient and the patient's family to create a more balanced, integrated person.

Our approach is humanistic. Our goal...to provide patients with the adaptive skills and self understanding to live in the world outside. If you believe in the reality of that goal, and would like to learn more about Sheppard Pratt's Chronic Schizophrenia Rehabilitation Program, please contact: Dr. David Waltos, Sheppard and Enoch Pratt Hospital, P.O. Box 6815, Baltimore, Maryland 21204. (301) 823-8200.



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Office of Disease Control and Epidemiology Newsletter

PREVENTIVE MEDICINE ADMINISTRATION
MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE

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JULY 1985

AIDS UPDATE - 6/26/85

	CASES	DEATHS
MARYLAND STATE TOTAL	170	75
METRO-BALTIMORE	86	45
SUBURBAN-WASHINGTON-D.C.	75	42

POPULATION GROUPS	
GAY OR BISEXUAL MEN	115 (68%)
IV DRUG USERS	26 (15%)
ALL OTHERS	29 (17%)

NATIONAL STATISTICS AS OF 6/29/85	
REPORTED CASES	11,271
REPORTED DEATHS	5,641

RUBELLA SUSCEPTIBILITY DEFINED

In June 1984, the Immunization Practices Advisory Committee (ACIP) issued a new statement on rubella immunization. This statement clarified their recommendation with regard to revaccinating individuals who were vaccinated for rubella prior to the first birthday. To quote the ACIP:

> "Persons can be considered immune to rubella only if they have documentation of (1) laboratory evidence of rubella immunity or (2) adequate immunization with rubella vaccine on or after the first birthday. All other children, adolescents, and adults...are considered susceptible and should be vaccinated if there are no contraindications."

This definition of acceptable rubella immunization has been adopted by the Department of Health and Mental Hygiene in consultation with the Med-Chi, and it will be phased in as a school requirement beginning with kindergarten pupils in September 1985. It will be progressively applied in one more grade each year until September 1997 when it will apply in all grades.

We urge all health providers to be alert to the age at which your patients were given rubella vaccine and revaccinate as necessary.

REVISED RECOMMENDATIONS FOR PREVENTING MALARIA IN TRAVELERS TO AREAS WITH CHLOROQUINE-RESISTANT PLASMODIUM FALCIPARUM

GENERAL ADVICE:

Travelers must be informed that regardless of the malaria prophylactic regimen employed, it is still possible to contract malaria. The symptoms of malaria, such as fever with chills and headache, demand medical attention as soon as possible and should not be presumptively ascribed by either the physician or traveler to a "flu-like" illness. Malaria symptoms can develop as early as 8 days after initial exposure in a malaria-endemic area and can appear months after departure from a malarious area, even after chemoprophylaxis is discontinued. It is important for travelers to understand that malaria can be effectively treated early in the course of the disease but that delays before the institution of appropriate therapy can have serious or even fatal consequences. Table 1 below lists the areas with reported chloroquine-resistant Plasmodium falciparum (CRPF).

TABLE 1. Areas with reported chloroquine-resistant *Plasmodium falciparum* (CRPF)*

AFRICA†
- Angola
- Burundi
- Central African Republic
- Comoros
- Gabon
- Kenya
- Madagascar
- Malawi
- Mozambique
- Namibia
- Rwanda
- Sudan (northern provinces)
- Tanzania
- Uganda
- Zaire (northeastern)
- Zambia (northeastern)

SOUTH AMERICA
- Bolivia
- Brazil**
- Colombia
- Ecuador††
- French Guiana
- Guyana
- Panama (east of the Canal Zone, including the San Bias Islands)
- Peru (northern provinces)
- Surinam
- Venezuela

ASIA
- Burma
- China (Hainan Island and southern provinces)
- Indonesia§
- Kampuchea†
- Laos¶
- Malaysia
- Philippines (Luzon, Basilan, Mindoro, Palawan, and Mindanao Islands; Sulu Archipelago)
- Thailand
- Vietnam

OCEANIA†
- Papua New Guinea
- Solomon Islands
- Vanuatu

INDIAN SUBCONTINENT†
- Bangladesh (north and east)
- India
- Pakistan (Rawalpindi)

*There is no malaria risk in urban areas unless otherwise indicated. This table should be used in conjunction with the text in determing appropriate prophylaxis.

†Malaria risk exists in most urban areas.

§Malaria risk exists in urban areas of Timor and Kalimantan provinces. Irian Jaya should be considered as Oceania.

¶Malaria risk exists in all urban areas except Vientiane.

**Malaria risk exists in urban areas of interior Amazon River region.

††Malaria risk exists in urban areas of Esmeraldas, Manabi, El Oro, and Guayas provinces (including city of Guayaquil).

PERSONAL PROTECTION MEASURES

Because of the nocturnal feeding habits of Anopheles mosquitoes, malaria transmission occurs primarily between dusk and dawn. Travelers must be advised of the importance of measures to reduce contact with mosquitoes during those hours. Such measures include remaining in well-screened areas, using mosquito nets, and wearing clothes that cover most of the body. Additionally, travelers should be advised to purchase insect repellent before travel to use on any exposed areas of skin. The most effective repellent is N,N diethylmetatoluamide (deet), an ingredient in many commercially available insect repellents. Travelers may also be advised to purchase a pyrethrum-containing flying insect spray to use in living and sleeping areas during even and nighttime hours.

DRUGS USED IN THE PROPHYLAXIS

Because of the risk of serious and sometimes fatal adverse reactions, it is no longer recommended that all travelers to areas with CRPF use Fansidar. Table 2 below lists the drugs used in the prophylaxis and presumptive treatment of malaria acquired in areas with CRPF.

TABLE 2. Drugs used in the prophylaxis and presumptive treatment of malaria acquired in areas with CRPF

Drug	Routine prophylaxis		Presumptive treatment	
	Adult dose	Pediatric dose	Adult dose	Pediatric dose
Chloroquine phosphate (Aralen®)	300 mg base (500 mg salt) orally, once/week	5 mg/kg base (8 3 mg/kg salt) orally, once/week, up to maximum adult dose of 300 mg base	Chloroquine is not recommended for the presumptive treatment of malaria acquired in areas of known chloroquine resistance.	
Amodiaquine (Camoquin®, Flavoquine®)*	400 mg base (520 mg salt) orally, once/week	7 mg/kg base (9 mg/kg salt) orally, once/week, up to maximum adult dose of 400 mg base	Amodiaquine is not recommended for the presumptive treatment of malaria acquired in areas of known chloroquine resistance.	
Pyrimethamine-sulfadoxine (Fansidar®)†	1 tablet (25 mg pyrimethamine and 500 mg sulfadoxine) orally, once/week	2-11 mos. 1/8 tab/wk 1-3 yrs 1/4 tab/wk 4-8 yrs ½ tab/wk 9-14 yrs ¾ tab/wk > 14 yrs 1 tab/wk	3 tablets (75 mg pyrimethamine and 1500mg sulfadoxine), orally, as a single dose	2-11 mos 1/4 tab 1-3 yrs ½ tab 4-8 yrs 1 tab 9-14 yrs 2 tabs > 14 yrs 3 tabs as a single dose
Doxycycline§	100 mg orally, once/day	> 8 years of age 2 mg/kg of body weight, orally/day up to adult dose of 100 mg/day	Tetracyclines are not recommended for the presumptive treatment of malaria	

*Unavailable in the United States but widely available overseas

†The use of Fansidar® is contraindicated in persons with histories of sulfonamide or pyrimethamine intolerance, in pregnancy at term, and in infants under 2 months of age. Physicians who prescribe the drug to be used as presumptive treatment in the event of a febrile illness when professional medical care is not readily available should ensure that such prescriptions are clearly labeled with instructions to be followed in the event of a febrile illness. If used as weekly prophylaxis, travelers should be advised to discontinue the use of the drug immediately in the event of a possible adverse effect, especially if any mucocutaneous signs or symptoms develop.

§The use of doxycycline is contraindicated in pregnancy and in children under 8 years of age. FDA considers the use of tetracyclines as antimalarials to be investigational. Physicians who prescribe doxycycline as malaria chemoprophylaxis should advise their patients to limit direct exposure to the sun to minimize the possibility of a photosensitivity reaction.

SHORT-TERM TRAVEL. For short-term travelers (3 weeks or less) to areas of Africa with CRPF, the weekly use of chloroquine alone is recommended. In all areas with CRPF, there is malaria caused by one or more species of Plasmodium (P. vivax, P. ovale, P. malariae) that remains sensitive to chloroquine. Chloroquine-sensitive P. falciparum may coexist with chloroquine-resistant parasites within a geographic area. In addition, these travelers (except those with histories of sulfonamide or pyrimethamine intolerance) should be given a single treatment dose of Fansidar (Table 2) to be kept in their possession during travel and should be advised to take it promptly in the event of a febrile illness during or after their travel when professional medical care is not readily available. It must be emphasized to travelers that such presumptive self-treatment of a possible malarial infection is only a temporary measure and that professional medical follow-up care as soon as possible is imperative. They should also be advised to continue weekly chloroquine prophylaxis after presumptive treatment with Fansidar.

Amodiaquine is not marketed in the United States. Another alternative is the use of daily doxycycline alone for travelers with previous histories of sulfonamide tolerance. Doxycycline is contraindicated in pregnancy and in children under 8 years of age. Photosensitivity is one of the possible side effects in all ages.

The use of proguanil is not recommended.

LONGER-TERM TRAVEL. Because persons with prolonged exposure in areas of CRPF transmission are at higher risk of acquiring malaria, the use of combined weekly prophylaxis with chloroquine and Fansidar (Table 2) can be considered. Physicians who advise such travelers and expatriate residents must take into consideration individual living conditions while in Africa, the availability of local medical care, and when possible, local malaria transmission patterns. The suitability of the regimen described above for short-term travelers should also be assessed. The potential benefit of the routine prophylactic use of Fansidar for these travelers must be weighed against the risk of a possible serious or fatal adverse reaction. If weekly use of Fansidar is prescribed, the traveler should be advised to discontinue it immediately in the event of a possible ill effect, especially if any mucocutaneous signs or symptoms, such as pruritus, erythema, rash, orogenital lesions, or pharyngitis, develop.

Adapted from the Morbidity and Mortality Weekly Report, April 12, 1985/Vol. 34/No. 14.


AFTER BREAKTHROUGH BLEEDING AND AMENORRHEA...
SHE'S ABOUT TO GIVE UP ON ORAL CONTRACEPTION.
NORLESTRIN®
1 mg norethindrone acetate and 50 mcg ethinyl estradiol tablets, USP 1/50
BECAUSE SOMETIMES A 50 IS PREFERABLE.
(see next page for brief summary of prescribing information)

Brief Summary of Prescribing Information
NORLESTRIN® (norethindrone acetate and ethinyl estradiol tablets, USP)

See section under **Special Notes on Administration and HOW SUPPLIED.**
Before prescribing, please see full prescribing information. A Brief Summary follows.

DESCRIPTION
Norlestrin Products are progestogen-estrogen combinations.

INDICATIONS AND USAGE
Norlestrin Products are indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

In clinical trials with Norlestrin 1/50 involving 25,983 therapy cycles, there was a pregnancy rate of 0.05 per 100 woman-years; in clinical trials with Norlestrin 2.5/50 involving 96,388 cycles, there was a pregnancy rate of 0.22 per 100 woman-years.

Dose-Related Risk of Thromboembolism from Oral Contraceptives: Studies have shown a positive association between the dose of estrogens in oral contraceptives and the risk of thromboembolism. It is prudent and in keeping with good principles of therapeutics to minimize exposure to estrogen. The oral contraceptive prescribed for any given patient should be that product which contains the least amount of estrogen that is compatible with an acceptable pregnancy rate and patient acceptance.

CONTRAINDICATIONS
1. Thrombophlebitis or thromboembolic disorders
2. A past history of deep-vein thrombophlebitis or thromboembolic disorders
3. Cerebral vascular or coronary artery disease
4. Known or suspected carcinoma of the breast
5. Known or suspected estrogen-dependent neoplasia
6. Undiagnosed abnormal genital bleeding
7. Known or suspected pregnancy (See WARNING No. 5)
8. Benign or malignant liver tumor which developed during the use of oral contraceptives or other estrogen-containing products.

WARNINGS

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

The use of oral contraceptives is associated with increased risk of several serious conditions including thromboembolism, stroke, myocardial infarction, hepatic adenoma, gallbladder disease, and hypertension. Practitioners prescribing oral contraceptives should be familiar with the following information relating to these risks.

1. *Thromboembolic Disorders and Other Vascular Problems.* An increased risk of thromboembolic and thrombotic disease associated with the use of oral contraceptives is well-established. Studies have demonstrated an increased risk of fatal and nonfatal venous thromboembolism and stroke, both hemorrhagic and thrombotic.

Cerebrovascular Disorders: In a collaborative study in women with and without predisposing causes, it was estimated that the risk of hemorrhagic stroke was 2.0 times greater in users than nonusers, and the risk of thrombotic stroke was 4.0 to 9.5 times greater.

Myocardial Infarction: An increased risk of myocardial infarction associated with oral contraceptives has been reported confirming a previously suspected association. These studies found that the greater the number of underlying risk factors (cigarette smoking, hypertension, hypercholesterolemia, obesity, diabetes, history of preeclamptic toxemia) for coronary artery disease, the higher the risk of developing myocardial infarction, regardless of whether the patient was an oral contraceptive user or not. Oral contraceptives, however, were found to be a clear additional risk factor.

It has been estimated that users who do not smoke (smoking is considered a major predisposing condition to myocardial infarction) are about twice as likely to have a fatal myocardial infarction as nonusers who do not smoke. Oral contraceptive users who are smokers have about a fivefold increased risk of fatal infarction compared to users who do not smoke, but about a tenfold to twelvefold increased risk compared to nonusers who do not smoke. The amount of smoking is also an important factor.

Risk of Dose: In an analysis of data, British investigators concluded that the risk of thromboembolism, including coronary thrombosis, is directly related to the dose of estrogen used in oral contraceptives, however, the quantity of estrogen may not be the sole factor involved.

Persistence of Risk: Two studies have suggested that an increased risk may persist for as long as 6 years after discontinuation of oral contraceptive use for cerebrovascular disease and 9 years for myocardial infarction. In addition, a prospective study suggested the persistence of risk for subarachnoid hemorrhage.

Estimate of Excess Mortality from Circulatory Diseases: The risk of diseases of the circulatory system is concentrated in older women, in those with a long duration of use, and in cigarette smokers.

A study of available data from a variety of sources concluded that the mortality associated with all methods of birth control is low and below that associated with childbirth, with the exception of oral contraceptives in women over 40 who smoke.

The risk of thromboembolic and thrombotic diseases associated with oral contraceptives increases with age after approximately age 30 and, for myocardial infarction, is further increased by hypertension, hypercholesterolemia, obesity, diabetes, or history of preeclamptic toxemia, and especially by cigarette smoking.

The physician and the patient should be alert to the earliest manifestations of thromboembolic and thrombotic disorders. Should any occur or be suspected, the drug should be discontinued immediately.

A fourfold to sixfold increased risk of postsurgery thromboembolic complications has been reported in users. If feasible, oral contraceptives should be discontinued at least four weeks before surgery of a type associated with an increased risk of thromboembolism or prolonged immobilization.

2. *Ocular Lesions.* Neuro-ocular lesions, such as optic neuritis or retinal thrombosis, have been associated with the use of oral contraceptives. Discontinue the oral contraceptive if there is unexplained sudden or gradual, partial, or complete loss of vision; onset of proptosis or diplopia; papilledema; or retinal vascular lesions.

3. *Carcinoma.* Long-term continuous administration of estrogen in certain animal species increases the frequency of carcinoma of the breast, cervix, vagina, and liver.

In humans, an increased risk of endometrial carcinoma associated with the prolonged use of exogenous estrogen in postmenopausal women has been reported. However, there is no evidence suggesting increased risk of endometrial cancer in users of conventional combination or progestogen-only oral contraceptives.

Studies found no evidence of increase in breast cancer in women taking oral contraceptives; however, an excess risk in users with documented benign breast disease was reported.

There is no confirmed evidence of an increased risk of cancer associated with oral contraceptives. Close clinical surveillance of users is, nevertheless, essential. In cases of undiagnosed persistent or recurrent abnormal vaginal bleeding, appropriate diagnostic measures should be taken to rule out malignancy. Women with a strong family history of breast cancer, or who have breast nodules, fibrocystic disease, or abnormal mammograms, should be monitored with particular care.

4. *Hepatic Tumors.* Benign hepatic adenomas have been found to be associated with oral contraceptives. Because hepatic adenomas may rupture and may cause death through intra-abdominal hemorrhage, they should be considered in women presenting abdominal pain and tenderness, abdominal mass, or shock.

A few cases of hepatocellular carcinoma have been reported in women taking oral contraceptives. The relationship of these drugs to this type of malignancy is not known at this time.

5. *Usage in or Immediately Preceding Pregnancy, Birth Defects in Offspring, and Malignancy in Female Offspring.* During early pregnancy, female sex hormones may seriously damage the offspring.

An increased risk of congenital anomalies, including heart defects and limb defects, has been reported with the use of oral contraceptives in pregnancy.

There is some evidence that triploidy and possible other types of polyploidy are increased among abortuses from women who become pregnant soon after ceasing oral contraceptives.

Pregnancy should be ruled out before continuing an oral contraceptive in any patient who has missed two consecutive menstrual periods. If the patient has not adhered to the schedule, the possibility of pregnancy should be considered at the time of the first missed period and oral contraceptives should be withheld until pregnancy has been ruled out. If pregnancy is confirmed, the patient should be apprised of the potential risks to the fetus and the advisability of continuation of the pregnancy should be discussed.

Women who discontinue oral contraceptives with the intent of becoming pregnant should use an alternate form of contraception for a period of time before attempting to conceive.

Administration of progestogen-only or progestogen-estrogen combinations to induce withdrawal bleeding should not be used as a test of pregnancy.

6. *Gallbladder Disease.* Studies report an increased risk of surgically confirmed gallbladder disease in users of oral contraceptives.

7. *Carbohydrate and Lipid Metabolic Effects.* Because decreased glucose tolerance has been observed in a significant percentage of patients, prediabetic and diabetic patients should be carefully observed while receiving oral contraceptives.

An increase in triglycerides and total phospholipids has been observed.

8. *Elevated Blood Pressure.* An increase in blood pressure has been reported in patients receiving oral contraceptives. The prevalence in users increases with longer exposure. Age is also strongly correlated with development of hypertension. Women who previously have had hypertension during pregnancy may be more likely to develop elevation of blood pressure.

9. *Headache.* Onset or exacerbation of migraine or development of headache of a new pattern which is recurrent, persistent, or severe, requires discontinuation of oral contraceptives.

10. *Bleeding Irregularities.* Breakthrough bleeding, spotting, and amenorrhea are frequent reasons for patients discontinuing oral contraceptives. In breakthrough bleeding, nonfunctional causes should be borne in mind. In undiagnosed abnormal bleeding from the vagina, adequate diagnostic measures are indicated to rule out pregnancy or malignancy.

Women with a past history of oligomenorrhea or secondary amenorrhea, or young women without regular cycles should be advised that they may have a tendency to remain anovulatory or to become amenorrheic after discontinuation of oral contraceptives.

11. *Ectopic Pregnancy.* Ectopic as well as intrauterine pregnancy may occur in contraceptive failures.

12. *Breast-Feeding.* Oral contraceptives may interfere with lactation. Furthermore, a small fraction of the hormonal agents in oral contraceptives has been identified in the milk of mothers receiving these drugs.

PRECAUTIONS
1. A complete medical and family history should be taken prior to the initiation of oral contraceptives. The pretreatment and periodic physical examinations should include special reference to blood pressure, breasts, abdomen, and pelvic organs, including Papanicolaou smear and relevant laboratory tests. As a general rule, oral contraceptives should not be prescribed for longer than one year without another examination.
2. Preexisting uterine leiomyomata may increase in size.
3. Patients with a history of psychic depression should be carefully observed and the drug discontinued if depression recurs to a serious degree.
4. Oral contraceptives may cause fluid retention and should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated.
5. Patients with a past history of jaundice during pregnancy have an increased risk of recurrence of jaundice. If jaundice develops, the medication should be discontinued.
6. Steroid hormones may be poorly metabolized and should be administered with caution in patients with impaired liver function.
7. Users may have disturbances in normal tryptophan metabolism, which may result in a relative pyridoxine deficiency.
8. Serum folate levels may be depressed.
9. The pathologist should be advised of oral contraceptive therapy when relevant specimens are submitted.
10. Certain endocrine and liver function tests and blood components may be affected.

(a) Increased sulfobromophthalein retention. (b) Increased prothrombin and factors VII, VIII, IX, and X; decreased antithrombin 3, increased norepinephrine-induced platelet aggregability. (c) Increased thyroid-binding globulin (TBG) leading to increased circulating total thyroid hormone. (d) Decreased pregnanediol excretion. (e) Reduced response to metyrapone test.

Drug Interactions: Reduced efficacy and increased incidence of breakthrough bleeding have been associated with concomitant use of rifampin. A similar association has been suggested with barbiturates, phenylbutazone, phenytoin sodium, tetracycline, and ampicillin.

ADVERSE REACTIONS
An increased risk of the following serious adverse reactions has been associated with oral contraceptives: thrombophlebitis, pulmonary embolism, coronary thrombosis, cerebral thrombosis, cerebral hemorrhage; hypertension; gallbladder disease, benign hepatomas, congenital anomalies.

There is evidence of an association between the following conditions and the use of oral contraceptives, although additional confirmatory studies are needed: mesenteric thrombosis, neuro-ocular lesions, eg, retinal thrombosis and optic neuritis.

The following adverse reactions have been reported in patients receiving oral contraceptives and are believed to be drug related: nausea and/or vomiting, usually the most common adverse reactions, occur in approximately 10% or less of patients during the first cycle. Other reactions, as a general rule, are seen much less frequently or only occasionally: gastrointestinal symptoms, breakthrough bleeding, spotting, change in menstrual flow, dysmenorrhea, amenorrhea during and after treatment, temporary infertility after discontinuance of treatment; edema; chloasma or melasma, breast changes, change in weight; change in cervical erosion and cervical secretion; possible diminution in lactation when given immediately postpartum, cholestatic jaundice; migraine; increase in size of uterine leiomyomata; rash (allergic), mental depression; reduced tolerance to carbohydrates, vaginal candidiasis; change in corneal curvature, intolerance to contact lenses.

The following adverse reactions have been reported and the association has been neither confirmed nor refuted: premenstrual-like syndrome; cataracts, changes in libido; chorea, changes in appetite; cystitis-like syndrome, headache, nervousness, dizziness, hirsutism, loss of scalp hair, erythema multiforme; erythema nodosum, hemorrhagic eruption, vaginitis; porphyria.

Special Notes on Administration
Menstruation usually begins two or three days, but may begin as late as the fourth or fifth day after discontinuing medication.

After several months on treatment, bleeding may be reduced to a point of virtual absence; reduced flow may be a result of medication and not indicative of pregnancy.

HOW SUPPLIED
Norlestrin [21] 1/50 is available in compacts each containing 21 tablets. Each tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

Norlestrin [21] 2.5/50 is available in compacts each containing 21 tablets. Each tablet contains 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

Norlestrin [Fe] 1/50 is available in compacts each containing 21 yellow tablets and 7 brown tablets. Each yellow tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Each brown tablet contains 75 mg of ferrous fumarate, USP. Available in packages of five compacts and packages of five refills.

Norlestrin [FE] 2.5/50 is available in compacts each containing 21 pink tablets and 7 brown tablets. Each pink tablet contains 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Each brown tablet contains 75 mg of ferrous fumarate, USP. Available in packages of five compacts and packages of five refills.

Norlestrin [28] 1/50 is available in compacts each containing 21 yellow tablets and 7 white inert tablets. Each yellow tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

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Morris Plains, New Jersey 07950

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PD-21-JA-2563-P-1(11-84)

BALANCED CALCIUM CHANNEL BLOCKADE!



Low incidence of side effects
CARDIZEM® (diltiazem HCl) produces an incidence of adverse reactions not greater than that reported with placebo therapy, thus contributing to the patient's sense of well-being.

Reduces angina attack frequency*
42% to 46% decrease reported in multicenter study.[1]

Increases exercise tolerance*
In Bruce exercise test,[2] control patients averaged 8.0 minutes to onset of pain; Cardizem patients averaged 9.8 minutes ($P<.005$).

*Cardizem is indicated in the treatment of angina pectoris due to coronary artery spasm and in the management of chronic stable angina (classic effort-associated angina) in patients who cannot tolerate therapy with beta-blockers and/or nitrates or who remain symptomatic despite adequate doses of these agents.

References:
1. Strauss WE, McIntyre KM, Parisi AF, et al: Safety and efficacy of diltiazem hydrochloride for the treatment of stable angina pectoris: Report of a cooperative clinical trial. Am J Cardiol 49:560-566, 1982.
2. Pool PE, Seagren SC, Bonanno JA, et al: The treatment of exercise-inducible chronic stable angina with diltiazem: Effect on treadmill exercise. Chest 78 (July suppl):234-238, 1980.

CARDIZEM®
(diltiazem HCl)

THE BALANCED CALCIUM CHANNEL BLOCKER

Please see full prescribing information on following page.

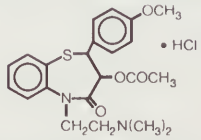
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PROFESSIONAL USE INFORMATION

cardizem®
(diltiazem HCl)
30 mg and 60 mg tablets

DESCRIPTION

CARDIZEM® (diltiazem hydrochloride) is a calcium ion influx inhibitor (slow channel blocker or calcium antagonist). Chemically, diltiazem hydrochloride is 1,5-Benzothiazepin-4(5H)one,3-(acetyloxy) -5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-, monohydrochloride,(+) -cis-. The chemical structure is:



Diltiazem hydrochloride is a white to off-white crystalline powder with a bitter taste. It is soluble in water, methanol, and chloroform. It has a molecular weight of 450.98. Each tablet of CARDIZEM contains either 30 mg or 60 mg diltiazem hydrochloride for oral administration.

CLINICAL PHARMACOLOGY

The therapeutic benefits achieved with CARDIZEM are believed to be related to its ability to inhibit the influx of calcium ions during membrane depolarization of cardiac and vascular smooth muscle.

Mechanisms of Action. Although precise mechanisms of its antianginal actions are still being delineated, CARDIZEM is believed to act in the following ways:

1. Angina Due to Coronary Artery Spasm: CARDIZEM has been shown to be a potent dilator of coronary arteries both epicardial and subendocardial. Spontaneous and ergonovine-induced coronary artery spasm are inhibited by CARDIZEM.
2. Exertional Angina: CARDIZEM has been shown to produce increases in exercise tolerance, probably due to its ability to reduce myocardial oxygen demand. This is accomplished via reductions in heart rate and systemic blood pressure at submaximal and maximal exercise work loads.

In animal models, diltiazem interferes with the slow inward (depolarizing) current in excitable tissue. It causes excitation-contraction uncoupling in various myocardial tissues without changes in the configuration of the action potential. Diltiazem produces relaxation of coronary vascular smooth muscle and dilation of both large and small coronary arteries at drug levels which cause little or no negative inotropic effect. The resultant increases in coronary blood flow (epicardial and subendocardial) occur in ischemic and nonischemic models and are accompanied by dose-dependent decreases in systemic blood pressure and decreases in peripheral resistance.

Hemodynamic and Electrophysiologic Effects. Like other calcium antagonists, diltiazem decreases sinoatrial and atrioventricular conduction in isolated tissues and has a negative inotropic effect in isolated preparations. In the intact animal, prolongation of the AH interval can be seen at higher doses.

In man, diltiazem prevents spontaneous and ergonovine-provoked coronary artery spasm. It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure and, in exercise tolerance studies in patients with ischemic heart disease, reduces the heart rate-blood pressure product for any given work load. Studies to date, primarily in patients with good ventricular function, have not revealed evidence of a negative inotropic effect; cardiac output, ejection fraction, and left ventricular end diastolic pressure have not been affected. There are as yet few data on the interaction of diltiazem and beta-blockers. Resting heart rate is usually unchanged or slightly reduced by diltiazem.

Intravenous diltiazem in doses of 20 mg prolongs AH conduction time and AV node functional and effective refractory periods approximately 20%. In a study involving single oral doses of 300 mg of CARDIZEM in six normal volunteers, the average maximum PR prolongation was 14% with no instances of greater than first-degree AV block. Diltiazem-associated prolongation of the AH interval is not more pronounced in patients with first-degree heart block. In patients with sick sinus syndrome, diltiazem significantly prolongs sinus cycle length (up to 50% in some cases).

Chronic oral administration of CARDIZEM in doses of up to 240 mg/day has resulted in small increases in PR interval, but has not usually produced abnormal prolongation. There were, however, three instances of second-degree AV block and one instance of third-degree AV block in a group of 959 chronically treated patients.

Pharmacokinetics and Metabolism. Diltiazem is absorbed from the tablet formulation to about 80% of a reference capsule and is subject to an extensive first-pass effect, giving an absolute bioavailability (compared to intravenous dosing) of about 40%. CARDIZEM undergoes extensive hepatic metabolism in which 2% to 4% of the unchanged drug appears in the urine. In vitro binding studies show CARDIZEM is 70% to 80% bound to plasma proteins. Competitive ligand binding studies have also shown CARDIZEM binding is not altered by therapeutic concentrations of digoxin, hydrochlorothiazide, phenylbutazone, propranolol, salicylic acid, or warfarin. Single oral doses of 30 to 120 mg of CARDIZEM result in detectable plasma levels within 30 to 60 minutes and peak plasma levels two to three hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3.5 hours. Desacetyl diltiazem is also present in the plasma at levels of 10% to 20% of the parent drug and is 25% to 50% as potent a coronary vasodilator as diltiazem. Therapeutic blood levels of CARDIZEM appear to be in the range of 50 to 200 ng/ml. There is a departure from dose-linearity when single doses above 60 mg are given; a 120-mg dose gave blood levels three times that of the 60-mg dose. There is no information about the effect of renal or hepatic impairment on excretion or metabolism of diltiazem.

INDICATIONS AND USAGE

1. **Angina Pectoris Due to Coronary Artery Spasm.** CARDIZEM is indicated in the treatment of angina pectoris due to coronary artery spasm. CARDIZEM has been shown effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (resting angina with ST-segment elevation occurring during attacks).
2. **Chronic Stable Angina (Classic Effort-Associated Angina).** CARDIZEM is indicated in the management of chronic stable angina. CARDIZEM has been effective in controlled trials in reducing angina frequency and increasing exercise tolerance.

There are no controlled studies of the effectiveness of the concomitant use of diltiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities.

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

1. **Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
2. **Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
3. **Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
4. **Acute Hepatic Injury.** In rare instances, patients receiving CARDIZEM have exhibited reversible acute hepatic injury as evidenced by moderate to extreme elevations of liver enzymes. (See PRECAUTIONS and ADVERSE REACTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS).

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vitro bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outweigh its potential risks in this situation.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences, as well as their frequency of presentation, are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3
asthenia (1.2%), AV block (1.1%). In addition, the following eve
were reported infrequently (less than 1%) with the order of prese
tion corresponding to the relative frequency of occurrence.

Cardiovascular:	Flushing, arrhythmia, hypotension, brady dia, palpitations, congestive heart fail syncope.
Nervous System:	Paresthesia, nervousness, somnolen tremor, insomnia, hallucinations, and amne
Gastrointestinal:	Constipation, dyspepsia, diarrhea, vomit mild elevations of alkaline phosphatase, SG SGPT, and LDH.
Dermatologic:	Pruritus, petechiae, urticaria, photosensiti
Other:	Polyuria, nocturia.

The following additional experiences have been noted:

A patient with Prinzmetal's angina experiencing episodes vasospastic angina developed periods of transient asymptom asystole approximately five hours after receiving a single 60- dose of CARDIZEM.

The following postmarketing events have been reported inf quently in patients receiving CARDIZEM: erythema multiforme; le kopenia; and extreme elevations of alkaline phosphatase, SG SGPT, LDH, and CPK. However, a definitive cause and effect betwe these events and CARDIZEM therapy is yet to be established.

OVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with oral diltiazem has been limit Single oral doses of 300 mg of CARDIZEM have been well tolerat by healthy volunteers. In the event of overdosage or exaggerat response, appropriate supportive measures should be employed addition to gastric lavage. The following measures may be consider

Bradycardia	Administer atropine (0.60 to 1.0 mg). If th is no response to vagal blockade, administ isoproterenol cautiously.
High-Degree AV Block	Treat as for bradycardia above. Fixed hig degree AV block should be treated with c diac pacing.
Cardiac Failure	Administer inotropic agents (isoproteren dopamine, or dobutamine) and diuretics.
Hypotension	Vasopressors (eg, dopamine or levarteren bitartrate).

Actual treatment and dosage should depend on the severity of t clinical situation and the judgment and experience of the treati physician.

The oral/LD_{50}'s in mice and rats range from 415 to 740 mg/ and from 560 to 810 mg/kg, respectively. The intravenous LD_{50}'s these species were 60 and 38 mg/kg, respectively. The oral LD_{50} dogs is considered to be in excess of 50 mg/kg, while lethality w seen in monkeys at 360 mg/kg. The toxic dose in man is not know but blood levels in excess of 800 ng/ml have not been associate with toxicity.

DOSAGE AND ADMINISTRATION

Exertional Angina Pectoris Due to Atherosclerotic Cor nary Artery Disease or Angina Pectoris at Rest Due to Cor nary Artery Spasm. Dosage must be adjusted to each patient needs. Starting with 30 mg four times daily, before meals and bedtime, dosage should be increased gradually (given in divide doses three or four times daily) at one- to two-day intervals unt optimum response is obtained. Although individual patients ma respond to any dosage level, the average optimum dosage rang appears to be 180 to 240 mg/day. There are no available data concer ing dosage requirements in patients with impaired renal or hepati function. If the drug must be used in such patients, titration should b carried out with particular caution.

Concomitant Use With Other Antianginal Agents:

1. **Sublingual NTG** may be taken as required to abort acut anginal attacks during CARDIZEM therapy.
2. **Prophylactic Nitrate Therapy**—CARDIZEM may be safe coadministered with short- and long-acting nitrates, but ther have been no controlled studies to evaluate the antangina effectiveness of this combination.
3. **Beta-blockers.** (See WARNINGS and PRECAUTIONS.)

HOW SUPPLIED

Cardizem 30-mg tablets are supplied in bottles of 100 (NDC 0088-1771-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1771-49). Each green tablet is engraved with MARION on one side and 1771 engraved on the other. CARDIZEM 60-mg scored tablets are supplied in bottles of 100 (NDC 0088-1772-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1772-49). Each yellow tablet is engraved with MARION on one side and 1772 on the other.

Issued 4/1/8

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The Library Page

"Toast Them, Burn Them, Roast Them"
Ultraviolet Ray Therapy: The Panacea of the 1920s and 1930s

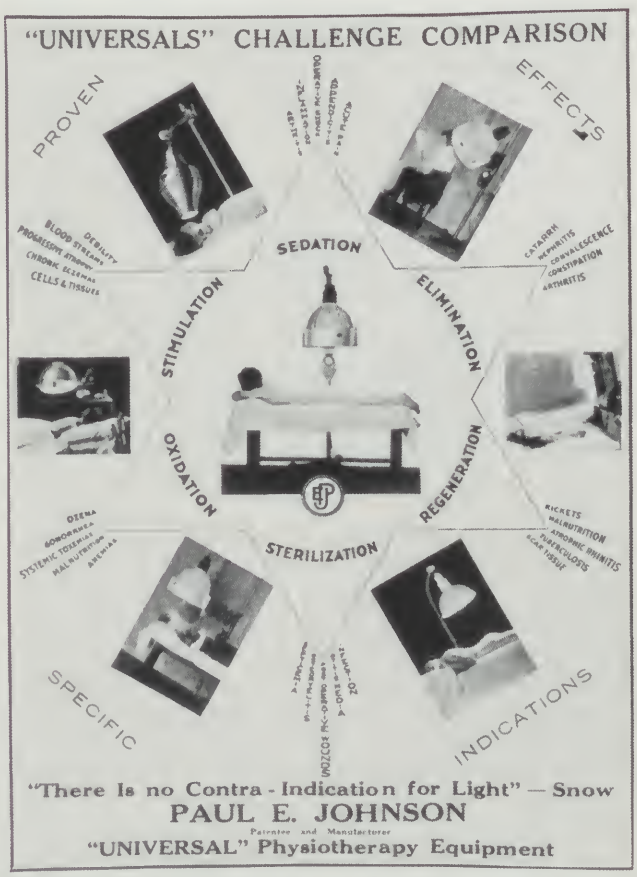
At the 1985 Annual Meeting of the Medical and Chirurgical Faculty, the History of Medicine division of the Faculty Library presented an exhibit on the use of ultraviolet ray therapy as a panacea in the 1920s and 1930s. Featured were two ultraviolet ray lamps from the library's museum collection as well as numerous photographs taken from contemporary medical texts. This article provides a brief overview of the history of ultraviolet ray therapy and its uses.

Ultraviolet radiation therapy (or actinotherapy) was a widely used physical therapy in the first third of the twentieth century. By the 1920s and 1930s ultraviolet radiation was claimed to be efficacious in treating a range of diseases, both internal and external, involving almost all organs of the body. While not the panacea it was thought to be, ultraviolet radiation was (and is) effective for certain conditions. Current literature tends to emphasize the dangers of ultraviolet light and the contraindications for its use; however, in the late 1920s adverse effects of ultraviolet therapy were only beginning to be recognized. The decline of widespread use of ultraviolet therapy was not due to its risks but rather its replacement by newly discovered and more efficient therapies such as antibiotics and vitamin supplements.

Through their research and experiments, late eighteenth and early nineteenth century scientists laid groundwork for modern actinotherapy. Carl Scheele's experiments showed that light at the violet end of the spectrum had stronger chemical properties than light at other parts of the spectrum. In 1801 Johann W. Ritter first used the term "ultravioletten" to describe invisible rays beyond the violet. Humphrey Davy became the first to produce artificial ultraviolet light in 1802; he created the first "carbon arc" by attaching two carbon pencils to a series of voltaic cells, bringing the two ends of the carbons together, and then pulling them apart. In 1821 Davy again produced artificial ultraviolet light by passing an electric current through a glass vacuum tube containing mercury.

During this time doctors were exploring various health applications of ultraviolet light. In an essay produced in 1796 and a thesis published in 1799, J. C. Ebermaier implied a relationship between sunlight and rickets. Bertrand maintained that heat and light were the same and related light to disease; he recongized both excess of light and underexposure as causal agents. In 1877 Downes and Blunt proved that light, especially at the violet end of the spectrum, could kill bacteria. In 1892 Marshall Ward showed that it was light that killed bacteria, rather than heat generated by light, and that ultraviolet rays were the most effective antibacteriants.

Throughout the nineteenth century and early twentieth century, doctors were claiming that sunlight was effective in treating a wide range of conditions including arthritis, tuberculosis, scurvy, rickets, melancholy, and venereal diseases. Special sanitariums, usually located in the country or near the ocean, began to emerge. August Rollier's alpine clinics achieved fame. The Swedish physician Niels Finsen won the Nobel Prize for medicine in 1903 for successfully treating tuberculosis with ultraviolet light. While Finsen, as well as others, thought the sun the best source of light, recourse to artificial light was sometimes necessary. Finsen built his own equipment and is credited as the first to use the carbon arc lamp in treatment. Finsen's clinic in Copenhagen, which employed artifical light in the treatment of lupus, was an important stimulus to the rise of actinotherapy. Doctors began to think of ultraviolet radiation therapy as a cure-all and used it to treat a variety of conditions.



Advertising and promotion An advertisement showing the wide range of conditions for which actinotherapy was considered therapeutic. From the *Am J Physical Ther* 2 (2), May 1925.

Medical and Chirurgical Faculty of the State of Maryland Library, 1211 Cathedral Street, Baltimore, MD 21201. Joseph E. Jensen, Librarian.

Conditions for Which Success Was Claimed

Alimentary Tract: appendiceal abscess, chronic colitis, chronic constipation, chronic inflammation of gall bladder, cirrhosis of the liver, hemorrhoids, hyperacidity of the stomach, ischiorectal abscess, postoperative adhesions, pyloric stenosis, pylorospasm, tuberculosis of the peritoneum and intestines, visceroptosis.

Circulatory System: anemia, arteriosclerosis, chlorosis, hemophilia, hypertension, hypotension, pericarditis, phlebitis, varicose veins.

Respiratory System: bronchial asthma, bronchitis, pertussis, pleural adhesions, pleurisy, pneumonia, pulmonary tuberculosis.

Nervous System: anterior poliomyelitis, chorea, disseminated sclerosis, encephalitis, hysteria, insanity, locomotor ataxia, myelitis, neurasthenia, neuritis, paralysis agitans, Raynaud's disease, sciatica.

Musculoskeletal System: fibrositis, fracture, fragilitas osseum, gonorrheal arthritis, gout, lumbago, myalgia, osteoarthritis, osteomalacia, osteomyelitic sinus, rheumatoid arthritis, synovitis, torticollis, tuberculosis of bones and joints.

Skin Diseases: acne, adenoma sebaceum, alopecia areata, alopecia prematura, alopecia senilis, boils, burns, carbuncle, chicken pox, cicatrix, cracked nipples, dermatitis herpetiformis, dermatitis venenata, dermatophytosis, eczema, erysipelas, erythema multiforme, erythema nodosum, folliculitis, herpes simplex, herpes zoster, impetigo, keloid, lichen planus, lupus vulgaris, neurodermatitis, onychia, paronychia, pernio, pityriasis rosea, pruritis, psoriasis, rhinophyma, scabies, scleroderma, seborrheic dermatitis, sycosis vulgaris, tinea versicolor, ulcer, urticaria, wart.

Genitourinary System: cystitis, nephritis, prostatitis, tuberculosis, urethritis.

Gynecologic Diseases: amenorrhea, bartholinitis, dysmenorrhea, endocervicitis, menorrhagia, metritis, oophoritis, tuberculous salpingitis, urethritis, vaginitis.

Eye, Ear, Nose, and Throat Diseases: blepharitis, choroiditis, conjunctivitis (chronic and catarrhal), corneal ulcer, herpes, hordeolum, phlyctenular keratitis, trachoma, tuberculosis.

Diseases of the Ear: otitis media, tuberculosis, ulcer of ear drum.

Diseases of the Nose: catarrh, ethmoiditis, hay fever, lupus, ozena, polyps, rhinitis, septal ulcer, sinusitis.

Diseases of the Throat: laryngismus, laryngitis, peritonsillar abscess, pharyngitis, tonsillar ulcer, tonsillitis, tuberculosis of larynx, Vincent's angina.

Diseases of the Mouth: dental caries, gingivitis, pyorrhea, stomatitis, ulcer.

Miscellaneous Conditions: adenomata, calcium metabolic disorders, chilblains, colds, eclampsia, lactation deficiency, malnutrition, mumps, rickets, spasmophilia, tetany, thymus enlargement, tic douloureux, tuberculosis.

Extracted from "History of Ultraviolet Therapy" by Sidney Licht in *Therapeutic Electricity and Ultraviolet Radiation.* 3rd ed. Edited by G. Keith Stillwell. Baltimore: Williams and Wilkins, 1983. [Original list from F. H. Krusen, *Light Therapy.* New York, 1933.]

After Finsen's success, others began to employ artificial ultraviolet light in treatment. Subsequently, lamps and treatment rooms were developed to treat large groups of patients collectively. In 1924 Steenbock showed that the therapeutic properties of ultraviolet light could be effectively stored in irradiated food and released after consumption. In 1926 Rosenheim and Webster discovered that ergosterol, a sterol found in plant and animal tissues, becomes vitamin D_2 when irradiated. Eventually, mass irradiation of children for vitamin D production was advocated and put into broad practice.

Use of ultraviolet radiation in vitamin D production is extremely rare today. In most cases, ultraviolet radiation therapy has been replaced by more effective and more easily administered antibiotics and vitamin supplements. Although ultraviolet radiation has been implicated in the production of skin cancers in light-skinned individuals as well as in the production of cataracts, actinotherapy still is considered appropriate for treating certain skin diseases, indolent ulcerations, surface infections, rheumatic diseases, and some ear, nose, and throat conditions. Operating arenas and other areas needing sterilized air often are sterilized by ultraviolet light.

Source

The above was abstracted from the following chapters: "History of Ultraviolet Therapy" by Sidney Licht; "Instrumentation for Ultraviolet Therapy" by William T. Anderson, Jr.; "Clinical Uses of Ultraviolet Radiation" by Bryan O. Scott in *Therapeutic Electricity and Ultraviolet Radiation.* 3rd ed. Edited by Keith G. Stilwell. Baltimore: Williams and Wilkins, 1983.

***DEBORAH K. WOOLVERTON,* Collection Manager**
***LISA A. MIX,* Assistant**
History of Medicine and Rare Book Collection

Mass irradiation of children for rickets and tuberculosis Ultraviolet radiation has been shown to be effective in increasing vitamin D production in living organisms as well as in foodstuffs like milk. Collective irradiation of undernourished children was practiced widely.



From *Raggi Ultravioletti.* 1 (6), Guigno 1925, p. 181.



From *Raggi Ultravioletti.* 1 (7), Luglio 1925, p. 206.

Selected Medical Literature Searches

The following are among the computerized medical literature searches provided to Med-Chi members during April 1985.

	No. of Citations
1. Aortocoronary bypass and internal mammary arteries	17
2. Behavioral medicine	16
3. Diabetes mellitus and contraceptives	30
4. Drugs and sports	41
5. Endoscopic removal of foreign bodies from the gastrointestinal system	22
6. Hodgkin's disease and bone neoplasms	10
7. Idiopathic intestinal pseudo-obstruction	19
8. Interferometry and retinal diseases	12
9. Psychological tests and Alzheimer's disease	17
10. Tuberculosis prevention with isoniazid	25

If you would like a copy of one of these searches or a search run on any biomedical topic, call or write the library.

SUSAN E. HARMAN
Reference and Circulation Librarian

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One Minute with Diabetes

Doctor, I have a friend with diabetes who tests her blood glucose at home several times daily. Could I control my diabetes if I tested my blood glucose? Is the test difficult to do? How much does it cost per test? Is it painful? Where can the equipment be bought?

One-minute blood glucose testing using capillary or venous blood has been available for more than twenty years. It was marketed mostly for physicians' offices and for screening purposes in emergency and delivery rooms. About five years ago the procedure began to be popular for the individual diabetic to monitor the control of his/her blood glucose. This was helped by the simplification of calibration and reducing the size of the equipment. Built-in timers and digital readout of blood glucose results were further helpful developments. Each year improved instruments appeared on the market.

The most popular instruments available are Glucometer (Ames Company), Accu-chek BG (Bio-Dynamics), and Glucoscan Plus (Lifescan, Inc.). Each manufacturer makes test strips for that particular machine. Test strips average 40 to 45 cents each. The instrument kits cost $150 to $200, depending on the accessories needed. For persons with little or no vision, the Bio-Dynamics Company has an instrument available to perform blood glucose testing.

Accuracy of the test method varies according to the ability of the person performing the procedure rather than the quality of the equipment. In general, an experienced person can get reproducible results within 10 percent of the readings of autoanalyzer methods.

Blood glucose testing strips of any of these methods can be read and visually compared with color-chip charts provided by the manufacturers. This provides considerable economy, but is somewhat less accurate than reading the results with the aid an of instrument. Again accuracy will vary with the experience and training of the individual doing the test.

Because of the inaccuracies of urine glucose testing and the uselessness of the procedure in the presence of a high renal threshold for glucose, self-blood glucose monitoring is essential for good control of diabetes mellitus. If the patient will use the equipment regularly and has the capacity to perform the test accurately, he/she should be referred to a surgical store or pharmacy carrying several types of machines for a demonstration. No instrument should be purchased from a store that will not demonstrate and instruct the purchaser in its proper use. The seller should provide a telephone number for response to questions if problems develop in testing at home. One manufacturer provides an 800 number for this purpose.

How often should one test? This varies from six times a day to once a day, depending on the lability of the test results. Ideally the blood glucose readings should be

Fasting	120 or less
One hour p.c.	180 or less
Three to four hours p.c.	120 or less

The glycohemoglobin test should be 8.5 percent or less (normal is 5.5 to 8.5 percent).

The patient doing self-blood glucose monitoring should bring his/her equipment to the physician's office at each visit to compare results with the office laboratory results on the same specimen. The physician can then review the patient's technique for performing the test as well as examine the cleanliness of the equipment.

Self-blood glucose monitoring is the biggest improvement that has occurred in diabetic care in many years. It should be recommended by physicians for all Type II diabetics who have difficulty maintaining good control.

DeWITT E. DeLAWTER MD
Editor

BIO PHOTOGRAPHIC SERVICES INC
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The Impaired Physician

The Target of Our Concern

Many people do not understand chemical dependency and are themselves social drinkers. Most physicians fall into this category. Unless physicians have special postgraduate education in alcoholism and other chemical dependencies, they are no different in this respect from laymen. Most medical school curricula do not incorporate modern concepts on early diagnosis and treatment. The majority of practicing physicians learn about alcoholism from attempting to care for terminal and preterminal hospitalized patients.

These patients seldom recover. They are difficult to care for: impatient, complaining, noncompliant, and often dishonest or deceitful. They seem unable to understand the seriousness of their illnesses and continue to drink despite efforts to persuade them not to. They often sign themselves out of hospitals at the first sign of physical improvement using transparent excuses for disregarding counsel to stay.

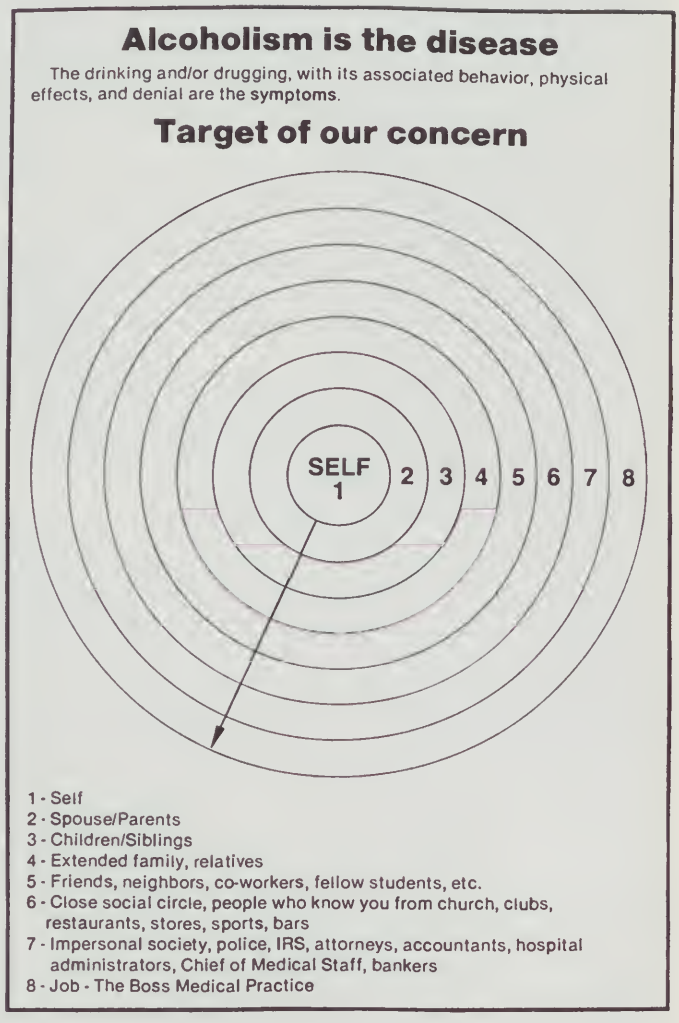
As a result of dealing almost solely with victims of advanced disease, physicians tend to view the illness as one that progresses from bad to worse. Like most diseases, however, alcoholism and other chemical dependencies progress from barely manifest to bad.

A criterion of "nonfunctioning on the job" has been adopted as a first signal of chemical dependency. In fact, it is nearly the last. Alcoholics do not spring into joblessness one day in their early forties because they drank too much for too long. Rather, they drank too much too long *because* they are alcoholics. The disease is not caused by alcohol, therefore, not drinking is not the cure: it is only a prerequisite for treatment.

The disease begins to manifest itself through feelings about self and feelings when using mood-altering drugs. Such feelings and the continued drug seeking they prompt inevitably lead to the earliest external signs: a disruption in expected or customary close relationships between self and parent, spouse, or significant other.

These relationships become strained because of Jekyll-and-Hyde behavior changes, discordance resulting from drug-induced amnesia, or repeated failure to meet commitments secondary to drug seeking or drug taking. Relationships, especially with children, require consistency for nourishment. With chemical dependency, inconsistency and unreliability become the hallmarks. Unpredictable and noisy arguments with spouse add to children's social uncertainties. Neighbor children make an early diagnosis; they do not come to play in a house where there is a drinking/drugged spouse, and they quickly make the connection between drinking and the resulting behavior. Ask any neighborhood ten year old which parent on their block has a problem.

When the disease becomes manifest in the outer rings, the inner rings contain witnesses of the antecedent destruction. The chemically dependent self clings to three massive deceptions:



"Nobody knows."
"I have it under control."
"I can handle it by myself."

Witnesses to the outer rings need to recognize that alcohol or drug use are not unlikely explanations for the progressive destruction of social and family relationships. By the time the employer suspects there is a problem, the victim probably is overwhelmed by the social destruction that has preceded the appearance of this outer marker. The private practitioner who is his/her own boss may be victimized further by this very circumstance and must depend on enlightened family and colleagues to intervene and confront.

Whether the target of concern is yourself or a sick colleague, your medical society can help. Find out how. Call 539-0872 or the Hotline 727-0120.

MARTIN J. VALASKE MD
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Inside Med-Chi

Building for 100 Years—75 Years Ago

For many years the Faculty has considered expanding its present facilities. A few years ago, Med-Chi acquired title to former School 49, adjacent to the Faculty, and planned to renovate it. In the past two years the process has gathered momentum, progressing through the throes of planning, designing, redesigning, reviewing bids, and awarding a contract for reconstruction, into office space for staff.

It is interesting to recall events that led in 1909 to establishment of Faculty headquarters at 1211 Cathedral Street. In 1896 the Faculty purchased a three-story house known as "Hamilton Terrace" at 847 North Eutaw Street. The Faculty made substantial improvements and renovations by creating a banquet hall in the basement, a 175-seat assembly room on the first floor, a library on the second floor, and an apartment for the resident librarian on the third floor. Despite these improvements the building soon proved inadequate. The meeting facilities were far too small to accommodate the rapidly growing Faculty membership. The expanding library quickly filled all available shelves. The roof and walls leaked, damaging the valuable collection of portraits and rare books. There was concern that the Faculty's assets and heritage could be lost in a fire.

At the 1901 annual meeting, a resolution was passed to liquidate the remaining $7,000 mortgage on Hamilton Terrace and "to raise a substantial building fund for the erection of a fireproof structure, designed specifically for the Society's needs." The next year the Treasurer reported all but $90 of the debt had been paid and the Faculty was in sound financial condition. The only other debt was $450 in notes to Faculty members. The report concluded with the suggestion

> We should begin at this meeting to consider the advisability of adding to our property or of purchasing a new home for our work. We cannot rest on our laurels until a larger building is secured and paid for out of our generosity.

A year passed with no activity. At the 1903 semiannual meeting Eugene F. Cordell MD raised the issue of the Faculty's inadequate quarters in his presidential address. "Let us carefully provide what further is necessary in the equipment of our society to fit it more thoroughly for the work it has to do," he urged. The rapid growth of the Faculty's membership was crowding the society out of Hamilton Terrace. In the eight years since the building had been purchased, membership had risen from 468 to over 700. The crowded meeting hall discouraged participation at annual meetings. Furthermore, the banquet hall was so crowded with stored books and journals that it could no longer be used for meals or exhibits.

Dr. Cordell endorsed a suggestion that the Faculty should appeal to the state legislature for assistance but pointed out that since the legislature would be overwhelmed with similar applications, members should expect far less than would be necessary. He warned:

> While building, we should adopt no half-way measures. We should build for the next hundred years at least, and such a structure as we need . . . will cost us at least $100,000.

In the following business meeting, a special committee was established to give the Faculty's pressing needs for a new building "immediate and constant supervision."

The Executive Committee did attempt to obtain state aid to erect a fire-proof building but, at the 1904 annual meeting, reported they had been unsuccessful. This was the only mention of building concerns in the minutes of the 1904 meeting.

At the 1904 semiannual meeting, the Faculty learned it was losing its most prestigious member, William Osler MD. He had accepted the position of *Regius Professor of Medicine* at Oxford University in England. At the 1905 annual meeting, Dr. Osler paid his farewell respects and gave an unforgettable heritage to the Medical and Chirurgical Faculty in his moving address, "Unity, Peace, and Concord." Following this event a group of Dr. Osler's friends led by Robert Johnson MD, presented the Faculty with a portrait of the great physician. Edward N. Brush MD, the President, used the occasion to urge Faculty members to support a renewed building drive. He accepted the portrait on behalf of the Faculty, admitting he did so with some embarrassment: there was no place to hang it. Dr. Brush admonished Faculty members to determine what they could afford for the new building, "and then to double it." This later became a theme for the building fund campaign.

In May 1906, new President S.T. Earle MD appointed Henry O. Reik MD to run a building campaign and charged him with submitting specific recommendations to advance the fund. Space problems were accentuated at this point by a request from the Association of Dentists in Maryland that the Faculty set aside for their special use a reading room for the safekeeping of their library. The dentists also wanted to rent the Faculty's hall for their public meetings.

1907

In April 1907, the Faculty Council held a special session to listen to a discouraged Building Committee report its lack of success in developing member interest and support. Failure to get aid from the legislature convinced the committee that before outside assistance could be obtained the Faculty must demonstrate its own interest by substantial contributions from the members. A.K. Bond MD suggested that Faculty offi-

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Public Relations Committee
James E. Bell MD, Chairman

cers empower the Building Committee to force the issue by taking available funds and purchasing a suitable site for the new building. The suggestion was adopted. At the Annual Meeting shortly thereafter, the Building Committee was officially reappointed with special powers:

> To solicit and collect monies for the purpose of providing a new Hall for the Faculty.
> To employ architects to prepare plans for the same.
> To select and acquire in the name of the Trustees a suitable site for the building.

Edward N. Brush MD was made chairman of the Committee; H.B. Jacobs MD, Secretary; and John Ruhrah MD, Treasurer.

During the Semiannual meeting that summer the Building Committee announced that the funds available (counting the estimated value of the presently owned property) were approaching $40,000 and the Committee was pushing its goal higher.

In November 1907 the Committee put its fund-raising campaign into full swing. With $43,129 available, a goal of $50,000 was set to be met by April 30, 1908. The theme was "Watch it Grow." On the title page of each issue of the Faculty's *Maryland Medical Journal* thereafter appeared a building sketch with blocks to be filled in with amounts available and amounts donated each week.

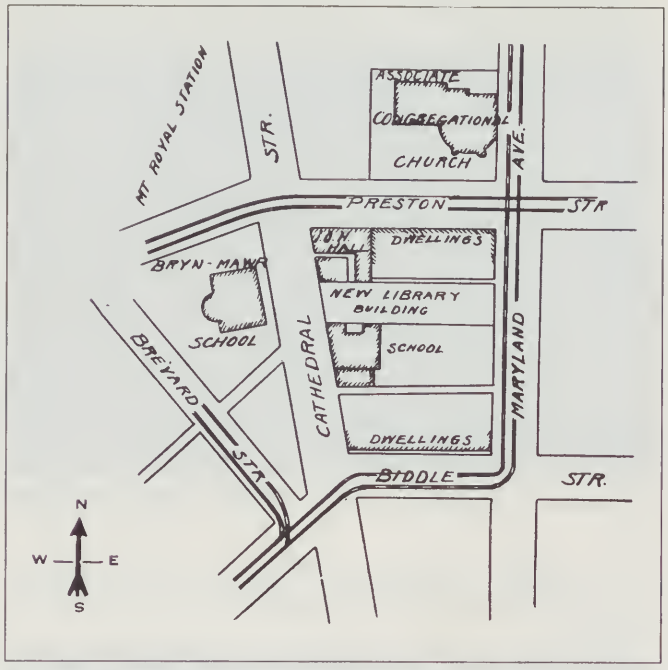
1908

By the last week in April the fund had reached a total of $50,753, well over the goal. The activity at last motivated the state legislature to bend somewhat to the Faculty's petitions: it appropriated $12,500, half what had been requested.

At the annual meeting, the Trustees announced they had purchased a large lot on Cathedral Street for a total cost of $24,096. Buoyed by the success of the campaign and the purchase of a site, the Building Committee expressed the hope that "one year hence" they could point "with excusable pride to a modern edifice, owned and controlled by this ancient and honorable Faculty." The next day G.M. Linthicum MD, Chairman of the Building Committee, moved that the House of Delegates empower the Faculty to borrow sufficient money to complete the new building. The motion, amended so that the amount would not exceed $25,000, was then approved.

On May 11, 1908, the Lady's Auxiliary and a Junior Auxiliary of physicians' daughters held a benefit at the Academy of Music for the new building. The occasion was used to announce the selection of Ellicott & Emmart as architects for the new building and to present tentative plans.

In July the Faculty inaugurated a new publication entitled *The Bulletin of the Medical and Chirurgical Faculty of Maryland*. The frontpiece of the first issue contained the architect's drawing of the facade of the new building and tentative floor plans. The building fund had raised almost $59,000, and an ambitious campaign was announced to raise an additional $40,000 before April 30, 1908. A new symbol for the fund drive was adopted: a thermometer with the mercury registering $59,000. The new slogan was "Help it Rise."





Excavation for the Med-Chi building, August 1908.

A Building Committee meeting was held on July 16 to award construction bids. The unanimous decision was to award the contract to J. Henry Miller & Son. The contract provided for completion of the structure within seven months. The electrical work was to be done by the John K. How Company, the plumbing by H.C. Bowman, the heating by the Crook-Kries Company, the fixtures by the Enos Company and the decorating by Benson and Company.

The Building Committee announced $15,000 was needed within thirty days to enable the contractor to begin active work on the new building. Funds were found and ground breaking occurred on August 7, 1908.



Two months' progress on the Med-Chi building, October 1908.

In the August *Bulletin* the Chairman announced another $15,000 would be needed over the next seven months.

At the House of Delegates meeting on September 16, Dr. Linthicum reported a loan of $25,000 had been secured from Maryland Savings Bank of Baltimore City. The loan was for five years at 5 percent per annum to be payed semiannually. Dr. Linthicum expressed doubt that additional funds could be raised and requested authorization to borrow an additional $15,000 if necessary. At the general session of the Faculty's membership, actions of the Building Committee and Faculty officers in negotiating the first loan were ratified, and the Committee was authorized to borrow an additional $15,000, if necessary, to complete the erection and improvements according to the architects' plans and specifications. It was announced that E. N. Brush MD, a former President who had championed the new building, was presenting the Faculty with the brick to be used in the building's front facade.

Following the Semiannual meeting, the Building Committee determined to name some of the rooms in the new building. The main auditorium was to be called Osler Hall; the library reading room, the Frick Room; the librarian's room, the Baker Room; and the social room, the Aaron Friedenwald Memorial Room. These rooms had been handsomely endowed by friends and relatives of the physicians whose names they bore. The Committee expressed the hope that the names of other prominent physicians might be memorialized by the future endowment of other rooms.

1909

In the January 1909 *Bulletin*, Dr. Linthicum announced the formation of an Interior Decorating Committee. Drs. Hugh H. Young, H.B. Jacobs, and R.B. Warfield were appointed to work in conjunction with Mr. Emmart (the architect) to decorate and furnish the entire building. Many features selected by these men still are visible. The building was entered through a spacious vestibule with marble base and architraves. The handsome stairway of solid masonry with marble steps, mahogany handrail, and wrought-iron balustrade was well lighted by a central skylight from above and windows on the landings. The library stack room allowed little light to enter from the outside in order to protect books from its adverse effects. The room was fitted with the best Snead metal fireproof stacks with a capacity for about 70,000 volumes. The room ran through the second and third stories; its fireproof door created an almost solid vault of concrete, brick, and steel.

In March, it was announced that the new building would be dedicated Thursday, May 13, and that the annual meeting would be postponed to coincide with the occasion. Following this notice there was a letter from the Faculty Secretary pleading for additional funds: $1,300 was needed immediately. To meet interest payments on the debt, it was necessary that two hundred members commit to paying a minimum of $10 per year for the next five years.

In April, an additional fund-raising event was announced. Max Brodel from the Department of Medical Illustration at the Johns Hopkins University Medical School had designed a bronze medal depicting the Faculty's seal on the face and the new building on the reverse. These medals were available to Faculty members for $1 each.

The proceedings of the dedication exercises appeared in the June 1909 issue of the *Bulletin*. In addition to a large number of renowned physicians, Maryland's Governor, Austin L. Crothers; Baltimore's Mayor, Honorable J. Barry Mahool, and other notable citizens including Honorable C.J. Bonaparte, Honorable Edwin Warfield, and General Leonard Wood attended the dedication.



The building was formally presented to the Faculty and citizens of Maryland by Edward N. Brush MD who had campaigned so long for the building.

But the man of the day was Dr. Osler. In a special ceremony, William Welch MD designated the grand hall as Osler Hall. Dr. Osler then delivered what was billed as the Annual Oration, a delightful work entitled "Old and New." (Offprints are now avidly sought by many collectors of Osler's writings.)

After the celebration, Faculty officers had to face the reality of indebtedness. More than $33,000 had been borrowed, and commitments to help pay off the debt were slow in coming. The Faculty continued to make payments on the interest, but it was several years before a special donation from Dr. Osler inspired sufficient contributions from Faculty members to pay off the principal.

An Object Lesson

When Dr. Cordell described the ideal building for the Faculty in his presidential address of 1903, he envisioned a building that would satisfy the needs of the Faculty for a hundred years or more. Such a building, he said, would cost at least $100,000. The present Faculty building was a compromise: only $90,000 was spent. This building served us well for seventy-five years, but now we are bursting at the seams. The Faculty staff has increased from four in 1909 to more than forty. The library owned just over 13,000 volumes in 1909. It now houses over 120,000 volumes in facilities designed for 70,000 volumes.

Renovating and restoring old School 49 into a new office building for the Faculty will cost sixteen times more than the present building cost in 1909. I wonder where we would be today if the Building Committee then had managed to find another $10,000. The additional twenty-five years that $10,000 would have bought might be an object lesson for today's Building Committee and officers.

JOSEPH E. JENSEN
Library Director



Library reading room at building's dedication, May 1909.



Commentary

Carcinogenic Risk Assessment: Concepts and Issues

M. L. BAECK PhD and MAX EISENBERG PhD

The past decade has been a period of intense public concern over the impact of technology on the environment. *Notabilia* since the 1970s are increases in the numbers of regulations introduced to protect the public from the carcinogenic effect of exposure to chemical substances. A chemical carcinogen is a cancer-producing substance that causes insult to susceptible cells, transforming them into tumor cells characterized by cellular malfunction and rapid proliferation. Carcinogenic risk assessment is proposed as an evaluation tool to infer, from existing information, the cancer risk of exposure to chemical substances.

Baeck is an environmental engineer, and Eisenberg is Director, Science and Environmental Health; both are employed by the Office of Environmental Programs, Department of Health and Mental Hygiene, State of Maryland, 201 West Preston Street, Baltimore, MD 21201.

Evaluation of the carcinogenic effects of a chemical substance (needed to develop and substantiate regulation) is confounded by a lack of experimental data for specific compounds and a paucity of both experimental and theoretical information on the mechanisms of cancerous growth. For example, the initiation of cancer appears to be characterized by a latency of onset, making it difficult to determine reliably a direct cause-and-effect relationship between exposure and incidence. Development of the condition is hypothesized as a multistage process where the outcome at each stage is influenced by an individual's inherent susceptibility and nutritional status as well as possible inhibition or enhancement through exposure to other substances. Lack of complete information suggests using an evaluation procedure that relies on inference of effect.

This article introduces the major concepts and issues relevant to the employment of a carcinogenic risk assessment under consideration in Maryland. The guidelines are an explicit statement of the options and subsequent decisions that must be made among alternate evaluation methods within each assessment step. They are advocated as a tool to facilitate consistency and to avoid subjectivity in the assessment. The guidelines are established through the evaluation, concatenation, and subsequent documentation of current toxic chemical substance assessment procedures. They will place the State's assessment procedures under scrutiny that should aid in identifying and emphasizing areas for continued research.

Definition

Carcinogenic risk assessment is the quantification of the carcinogenic risk of exposure of individuals or populations to a chemical substance. Giving explicit consideration to the uncertainties inherent in each step of the assessment, the procedure quantifies the probability of an increased incidence of cancer related to exposure to specified quantities of known or suspected carcinogens.

Many toxic substance evaluation situations can be effectively assessed for risk. The consistency of the assessment procedure when applied to different situations allows effective comparison of various investigative priority schemes. The assessment procedure can serve as a framework for evaluating the results of multimedia chemical substance monitoring. The quantitative estimate of risk can be used in the design of preventive strategies and in the decision to monitor or to regulate by continuing, restricting, or banning use of a chemical substance.

A major advantage of the proposed risk assessment when applied to these situations is the provision (through the risk-assessment guidelines) of a centralized assessment procedure. Resolution of many issues encountered in a risk assessment requires input from professionals with expertise in different fields of study. Documentation of these issues in the assessment guidelines will aid the practitioner in a thorough and efficient investigation of a particular situation.

Risk Assessment Procedure

In an identified situation, the attendant risk assessment procedure is divided into these steps by the National Research Council.

- Hazard identification
- Dose-response relationship
- Exposure assessment
- Risk characterization

The first two steps are situation independent and are categorized as hazard assessment. The result of this assessment in conjunction with the result of the site-specific exposure assessment are summarized in the risk characterization step. It should be noted that a zero or acceptable value at any assessment step can waive the necessity of assessment at subsequent steps.

Hazard identification is determining whether a chemical substance causes an increase in the incidence of cancer. It involves evaluating both the nature and significance of causal evidence. Evidence of chemical carcinogen hazard can originate from four sources: epidemiological studies on human populations, bioassays on experimental animals, short-term tests for mutagenicity or cell transformation that have been shown to

correlate with carcinogenicity, and chemical structure relationships to known carcinogens. This evidence is available through literature review of documents such as Cancer Line, Medline, Toxic Line, Chemline, information exchange with federal agencies such as the Environmental Protection Agency (EPA), National Institute for Occupational Safety and Health (NIOSH), Occupational Safety and Health Administration (OSHA), National Cancer Institute (NCI), National Institute of Health (NIH), National Institute of Environmental Health Sciences (NIEHS), Food and Drug Administration (FDA), Center for Disease Control (CDC), National Center for Health Statistics (NCHS), and state agencies that have developed such inventories.

The relevance and validity of the information obtained from these sources must be evaluated considering size of the data base, scientific quality of the analysis, and accessibility of the information. Within the framework of comprehensive risk-assessment guidelines, these hazard identification issues are addressed:

(a) Determination of the objective (adverse health effect) of the hazard assessment (that is, incidence of malignant tumors, incidence of benign tumors).
(b) Determination of appropriate source of information (for example, EPA, NIOSH, Chemline).
(c) Development of protocol for examination of validity of the data to determine the precision and an acceptable level of statistical significance.
(d) Determination of significance of data if route of exposure analyzed differs from that of the population at risk.
(e) Development of principles to evaluate contradictory hazard identification results.
(f) Development of principles to guide compensatory methods when data or evidence is judged not substantial.

The **dose-response assessment** is the estimation of the potency of a chemical substance through evaluating the relation between administered or received dose and incidence of cancer. The assessment usually requires adjustment of experimental animal hazard identification data to health effects in humans and extrapolation of the effects from high experimental dosage to lower dosage that may be experienced by the public. A threshold dose, below which no effect is indicated, has not been scientifically established for chemical carcinogenesis. Several nonthreshold high-to-low extrapolation models are in use and show some discrepancy in predicting effects outside the observable range of dosage. A comprehensive set of risk-assessment guidelines will help resolve these problems by:

(a) Determining appropriate high-to-low dose extrapolation models (dichotomous-response models, time-to-response models).
(b) Developing a basis for the correlation between experimental animals and humans (body weight ratio, body surface area ratio, life-span ratio).
(c) Determining commensurable units of dosage from different media.
(d) Determining the relationship between biological ("effective") dose and external dose as a function of different modes of exposure.
(e) Maintaining consistency between or development of deterministic models to relate the time span of exposure to estimate potency and the time span of exposure to the population at risk.

The goal of **exposure assessment** is to determine the chemical substance transport media and the site demography to estimate the concentration of a substance and the number of people exposed to it. For each potential route of exposure, an effort must be made to evaluate the frequency, magnitude, and duration of an exposure event and the number and susceptibility of people affected. In addition, the confounding effects of simultaneous exposure through multiple media need investigation. The risk assessment guidelines will:

(a) Determine a basis to define the exposed population group.
(b) Determine a protocol to evaluate the effects of confounding factors within the exposed population group.
(c) Examine different mathematical models and measurement techniques for the transport phenomena.
(d) Determine an efficacious protocol to assess potential exposure through multiple media.
(e) Determine a commensurable dosage unit for multimedia exposure.
(f) Develop a reference carcinogenic source inventory within the state.

Risk Characterization

The risk associated with a chemical carcinogen depends on the potency of the chemical carcinogen and the extent of exposure of a population. These two factors, evaluated in the hazard assessment step and the exposure assessment step respectively are used to estimate the probability of an increased incidence of cancer. Pertinent to the characterization is the documentation of the sources and magnitude of uncertainty in the risk estimate. These **risk characterization** issues will be addressed in the assessment guidelines:

(a) Determination of the objective of the risk assess-

ment procedure, (that is, probability of increased incidence in the most highly exposed population or on a composite average of the exposed population).

(b) Determination and presentation of the uncertainties in the procedure.

(c) Determination of the magnitude of the safety factors incorporated into the assessment procedure considering the source and validity of the experimental data.

(d) Determination of commensurable units of risk for interchemical comparison and potential risk/benefit analysis.

The issues addressed in each of the assessment steps pertain to a single chemical substance evaluation and are not proposed as all inclusive. The lists may be amended as the guidelines are developed in more detail and as research continues on the use of risk assessment to evaluate chemical carcinogenesis. For example, several short-term chronic (biological) tests and mutagenicity tests for hazard identification and dose-response assessment of complex mixtures are in stages of development and should be incorporated into the risk-assessment guidelines. A set of uniform carcinogenic risk assessment guidelines will allow for periodic review and feedback evaluation of the assessment procedures as information and expertise is gained.

Conclusion

Risk assessment is a tool for the evaluation of the potential carcinogenic effects of a chemical substance on an exposed population. The risk assessment procedure requires assessment of the potency of the chemical substance and of the population exposed in order to quantify the probability of an increased incidence of cancer. Development of and adherence to a set of comprehensive assessment guidelines is suggested as a means by which the state can address and attempt to resolve the conflicting issues within each step of the procedure. The guidelines, developed through evaluation and documentation of current assessment procedures, are posed to provide Maryland with a centralized and comprehensive method of stating and addressing the carcinogenic substance evaluation problem.

A risk-assessment procedure can be employed as an evaluation tool for the analysis and development of preventive strategies and regulation, the evaluation of site-specific incidences such as a hazardous substance spill, the analysis of multiple-media monitoring results, and the comparison and subsequent ranking of multiple hazardous substance investigations. It is important to stress that the quantitative estimate of risk, inferred from the best available yet often incomplete information, possesses a degree of uncertainty. Analysis of this uncertainty is an integral part of the risk-assessment procedure and should be considered in any regulatory decision-making process that evaluates carcinogenic risk.

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Medicolegal Hotline

for any emergency

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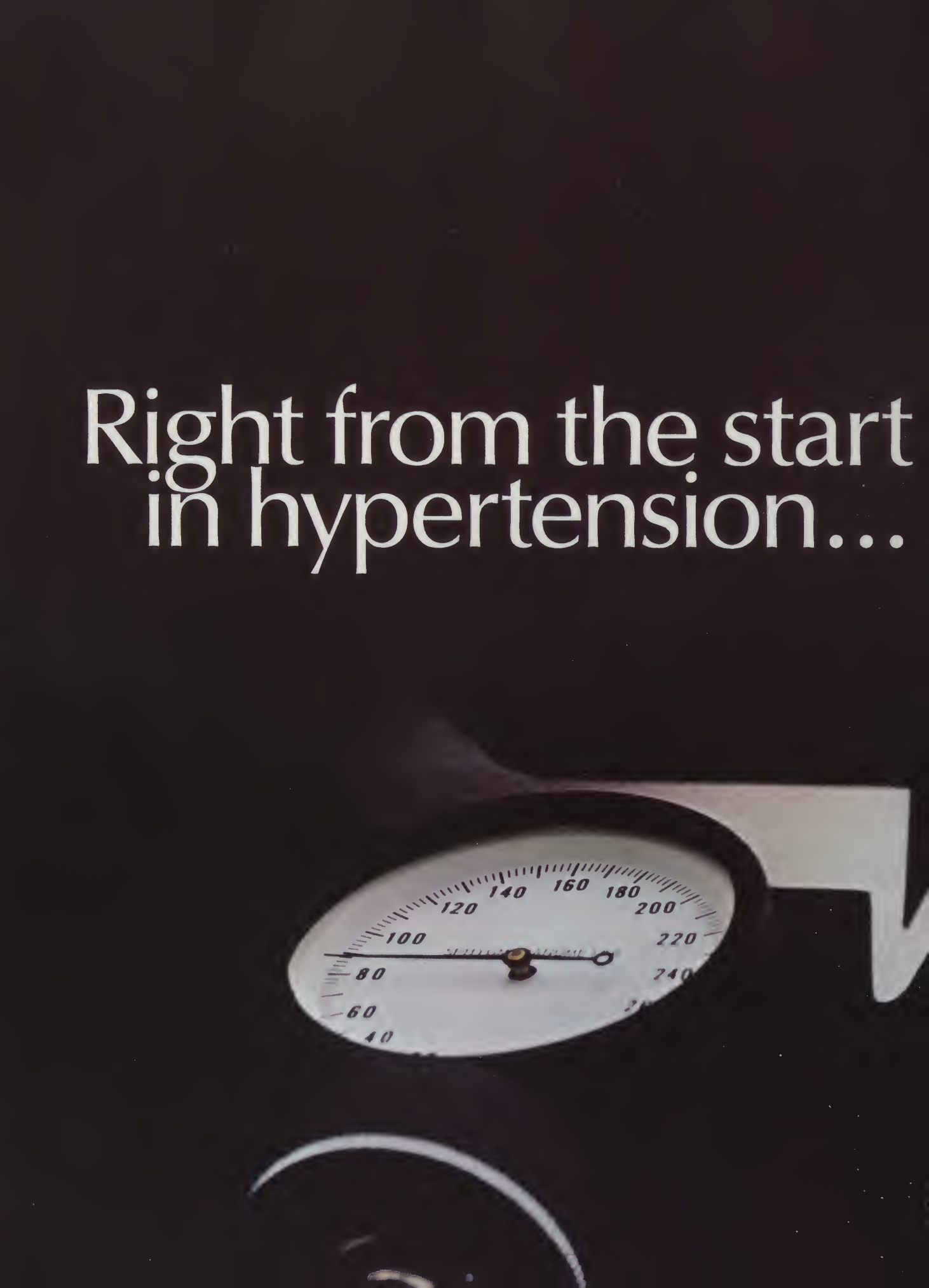
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Once-daily INDERAL LA (propranolol HCl) for smooth blood pressure control without the potassium problems of diuretics

Once-daily INDERAL LA (propranolol HCl) avoids the risk of diuretic-induced ECG abnormalities due to hypokalemia.[1,2] In addition, INDERAL LA preserves potassium balance without additive agents or supplements while providing simple, well-tolerated therapy with broad cardiovascular benefits.

Once-daily INDERAL LA for the cardiovascular benefits of the world's leading beta blocker

Simply start with 80 mg once daily. Dosage may be increased to 120 mg to 160 mg once daily as needed to achieve additional control.

Like conventional INDERAL tablets, INDERAL LA should not be used in the presence of congestive heart failure, sinus bradycardia, heart block greater than first degree, and bronchial asthma.

For beta-1/beta-2 blockade

Once-daily

INDERAL LA

(PROPRANOLOL HCl) LONG ACTING CAPSULES

80 mg 120 mg 160 mg

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Please see brief summary of prescribing information on the next page for further details

Once-daily For beta-1/beta-2 blockade INDERAL® LA (PROPRANOLOL HCl) LONG ACTING CAPSULES



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BRIEF SUMMARY *(FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE CIRCULAR.)*

INDERAL® LA brand of propranolol hydrochloride **(Long Acting Capsules)**

DESCRIPTION. Inderal LA is formulated to provide a sustained release of propranolol hydrochloride. Inderal LA is available as 80 mg, 120 mg, and 160 mg capsules.

CLINICAL PHARMACOLOGY. INDERAL is a nonselective beta-adrenergic receptor blocking agent possessing no other autonomic nervous system activity. It specifically competes with beta-adrenergic receptor stimulating agents for available receptor sites. When access to beta-receptor sites is blocked by INDERAL, the chronotropic, inotropic, and vasodilator responses to beta-adrenergic stimulation are decreased proportionately.

INDERAL LA Capsules (80, 120, and 160 mg) release propranolol HCl at a controlled and predictable rate. Peak blood levels following dosing with INDERAL LA occur at about 6 hours and the apparent plasma half-life is about 10 hours. When measured at steady state over a 24-hour period the areas under the propranolol plasma concentration-time curve (AUCs) for the capsules are approximately 60% to 65% of the AUCs for a comparable divided daily dose of INDERAL tablets. The lower AUCs for the capsules are due to greater hepatic metabolism of propranolol, resulting from the slower rate of absorption of propranolol. Over a twenty-four (24) hour period, blood levels are fairly constant for about twelve (12) hours then decline exponentially.

INDERAL LA should not be considered a simple mg for mg substitute for conventional propranolol and the blood levels achieved do not match (are lower than) those of two to four times daily dosing with the same dose. When changing to INDERAL LA from conventional propranolol, a possible need for retitration upwards should be considered especially to maintain effectiveness at the end of the dosing interval. In most clinical settings, however, such as hypertension or angina where there is little correlation between plasma levels and clinical effect, INDERAL LA has been therapeutically equivalent to the same mg dose of conventional INDERAL as assessed by 24-hour effects on blood pressure and on 24-hour exercise responses of heart rate, systolic pressure and rate pressure product. INDERAL LA can provide effective beta blockade for a 24-hour period.

The mechanism of the antihypertensive effect of INDERAL has not been established. Among the factors that may be involved in contributing to the antihypertensive action are (1) decreased cardiac output, (2) inhibition of renin release by the kidneys, and (3) diminution of tonic sympathetic nerve outflow from vasomotor centers in the brain. Although total peripheral resistance may increase initially, it readjusts to or below the pretreatment level with chronic use. Effects on plasma volume appear to be minor and somewhat variable. INDERAL has been shown to cause a small increase in serum potassium concentration when used in the treatment of hypertensive patients.

In angina pectoris, propranolol generally reduces the oxygen requirement of the heart at any given level of effort by blocking the catecholamine-induced increases in the heart rate, systolic blood pressure, and the velocity and extent of myocardial contraction. Propranolol may increase oxygen requirements by increasing left ventricular fiber length, end diastolic pressure and systolic ejection period. The net physiologic effect of beta-adrenergic blockade is usually advantageous and is manifested during exercise by delayed onset of pain and increased work capacity.

In dosages greater than required for beta blockade, INDERAL also exerts a quinidine-like or anesthetic-like membrane action which affects the cardiac action potential. The significance of the membrane action in the treatment of arrhythmias is uncertain.

The mechanism of the antimigraine effect of propranolol has not been established. Beta-adrenergic receptors have been demonstrated in the pial vessels of the brain.

Beta receptor blockade can be useful in conditions in which, because of pathologic or functional changes, sympathetic activity is detrimental to the patient. But there are also situations in which sympathetic stimulation is vital. For example, in patients with severely damaged hearts, adequate ventricular function is maintained by virtue of sympathetic drive which should be preserved. In the presence of AV block, greater than first degree, beta blockade may prevent the necessary facilitating effect of symoathetic activity on conduction. Beta blockade results in bronchial constriction by interfering with adrenergic bronchodilator activity which should be preserved in patients subject to bronchospasm.

Propranolol is not significantly dialyzable.

INDICATIONS AND USAGE. Hypertension: INDERAL LA is indicated in the management of hypertension; it may be used alone or used in combination with other antihypertensive agents, particularly a thiazide diuretic. INDERAL LA is not indicated in the management of hypertensive emergencies.

Angina Pectoris Due to Coronary Atherosclerosis: INDERAL LA is indicated for the long-term management of patients with angina pectoris.

Migraine: INDERAL LA is indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established and propranolol is not indicated for such use.

Hypertrophic Subaortic Stenosis: INDERAL LA is useful in the management of hypertrophic subaortic stenosis, especially for treatment of exertional or other stress-induced angina, palpitations, and syncope. INDERAL LA also improves exercise performance. The effectiveness of propranolol hydrochloride in this disease appears to be due to a reduction of the elevated outflow pressure gradient which is exacerbated by beta-receptor stimulation. Clinical improvement may be temporary.

CONTRAINDICATIONS. INDERAL is contraindicated in 1) cardiogenic shock; 2) sinus bradycardia and greater than first degree block; 3) bronchial asthma; 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with INDERAL.

WARNINGS. CARDIAC FAILURE: Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or INDERAL should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of INDERAL therapy. Therefore, when discontinuance of INDERAL is planned the dosage should be gradually reduced over at least a few weeks, and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If INDERAL therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute INDERAL therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema)—PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. INDERAL should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY: The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

INDERAL (propranolol HCl), like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, e.g., dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOGLYCEMIA: Beta-adrenergic blockade may prevent the appearance of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more difficult to adjust the dosage of insulin.

THYROTOXICOSIS: Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol does not distort thyroid function tests.

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS. *General:* Propranolol should be used with caution in patients with impaired hepatic or renal function. INDERAL (propranolol HCl) is not indicated for the treatment of hypertensive emergencies.

Beta adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should be told that INDERAL may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

Clinical Laboratory Tests: Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS. Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if INDERAL is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

Pregnancy. Pregnancy Category C. INDERAL has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose.

There are no adequate and well-controlled studies in pregnant women. INDERAL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: INDERAL is excreted in human milk. Caution should be exercised when INDERAL is administered to a nursing woman.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS. Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: bradycardia, congestive heart failure, intensification of AV block, hypotension; paresthesia of hands; thrombocytopenic purpura; arterial insufficiency, usually of the Raynaud type.

Central Nervous System: lightheadedness; mental depression manifested by insomnia, lassitude, weakness, fatigue; reversible mental depression progressing to catatonia; visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Gastrointestinal: nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory: bronchospasm.

Hematologic: agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-Immune: In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: alopecia, LE-like reactions, psoriasiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

DOSAGE AND ADMINISTRATION. INDERAL LA provides propranolol hydrochloride in a sustained-release capsule for administration once daily. If patients are switched from INDERAL tablets to INDERAL LA capsules, care should be taken to assure that the desired therapeutic effect is maintained. INDERAL LA should not be considered a simple mg for mg substitute for INDERAL. INDERAL LA has different kinetics and produces lower blood levels. Retitration may be necessary especially to maintain effectiveness at the end of the 24-hour dosing interval.

HYPERTENSION—*Dosage must be individualized.* The usual initial dosage is 80 mg INDERAL LA once daily, whether used alone or added to a diuretic. The dosage may be increased to 120 mg once daily or higher until adequate blood pressure control is achieved. The usual maintenance dosage is 120 to 160 mg once daily. In some instances a dosage of 640 mg may be required. The time needed for full hypertensive response to a given dosage is variable and may range from a few days to several weeks.

ANGINA PECTORIS—*Dosage must be individualized.* Starting with 80 mg INDERAL LA once daily, dosage should be gradually increased at three to seven day intervals until optimum response is obtained. Although individual patients may respond at any dosage level, the average optimum dosage appears to be 160 mg once daily. In angina pectoris, the value and safety of dosage exceeding 320 mg per day have not been established.

If treatment is to be discontinued, reduce dosage gradually over a period of a few weeks (see WARNINGS).

MIGRAINE—*Dosage must be individualized.* The initial oral dose is 80 mg INDERAL LA once daily. The usual effective dose range is 160-240 mg once daily. The dosage may be increased gradually to achieve optimum migraine prophylaxis. If a satisfactory response is not obtained within four to six weeks after reaching the maximum dose, INDERAL LA therapy should be discontinued. It may be advisable to withdraw the drug gradually over a period of several weeks.

HYPERTROPHIC SUBAORTIC STENOSIS—80-160 mg INDERAL LA once daily.

PEDIATRIC DOSAGE—At this time the data on the use of the drug in this age group are too limited to permit adequate directions for use.

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Clinical Magnetic Resonance Imaging

JOHN L. SHERMAN MD, CHARLES M. CITRIN MD, and BRUCE J. BOWEN MD

What became a revolution in diagnostic medicine began as an invention of the physicists and the tool of the biochemists. In 1946, Edward Purcell, from Harvard, and Felix Bloch, from Stanford, reported on nuclear magnetic resonance (NMR) research. They were awarded the Nobel Prize for physics in 1952. NMR had an impressive influence on disciplines such as physics, chemistry, and biochemistry and became a standard method of spectroscopic investigation of atomic and molecular structure in all forms of matter. It was not until 1973, however, that Paul Lauterbur produced the first two-dimensional proton images at Stony Brook University in New York.[1] His work quickly led to medical proton (hydrogen) imaging.

Dr. Sherman is Clinical Assistant Professor at the Uniformed Services University of the Health Sciences, Bethesda, MD. Dr. Citrin is Clinical Associate Professor of Radiology at the George Washington University Medical Center, Washington, DC. All three authors are with Magnetic Imaging of Washington and The Neurology Center, PA, Chevy Chase, MD.

Extensive research into magnetic resonance (MR) imaging has produced diagnostic-quality images that continue to improve (Figure 1). These images are familiar because they superficially resemble x-ray CT scans. However, they are radically different since they represent a display of tissue properties very foreign to our everyday x-ray experience. Although CT scanning has proved to be an extremely useful diagnostic tool, the information its images provide is basically anatomical; it tells little about the functional or physiological state of the internal organs. Many pathological lesions are so similar to those of the surrounding tissues that the lesions can go undetected in the CT scan unless they change the size or shape of the organ.

MR, on the other hand, provides excellent image contrast due to the inherent tissue differences in NMR properties. These tissue-contrast parameters include hydrogen density, the state of motion of the protons (blood flow), and relaxation times (called T1 and T2), which represent the behavior of hydrogen protons within tissue placed in a strong magnetic field. Striking tissue contrast can be achieved by balancing effects of different tissue parameters. Equally important, this contrast is achieved without use of ionizing radiation or iodinated contrast. Solid materials, such as cortical bone, have such a short relaxation time that they contribute little signal to the image. Hence cortical bone is "invisible" in the image and does not distort the surrounding signals. Artifact-free images are thus possible for regions poorly visualized by CT.

The complexity and abundance of MR methods and variations leave the clinical radiologist with a befuddling nomenclature and an unfamiliar set of data to analyze; yet it is this complexity that affords insights into tissue characterization and detection of disease. While this confers a remarkable versatility on MR, it can lead to problems. For example, a combination of relaxation times in a given lesion may create poor or even no contrast with the lesion's surroundings when using only one spin sequence; however, a striking contrast appears when using another sequence in which the resulting signal is weighted differently by the relaxation times.

History

Neurological applications of CT were the first acclaimed and then accepted. MR has followed a similar path but with more rapidity than CT and is now poised to replace CT as the method of choice for brain evaluation. MRI's better contrast resolution is evidenced by better differentiation of white and gray matter; more

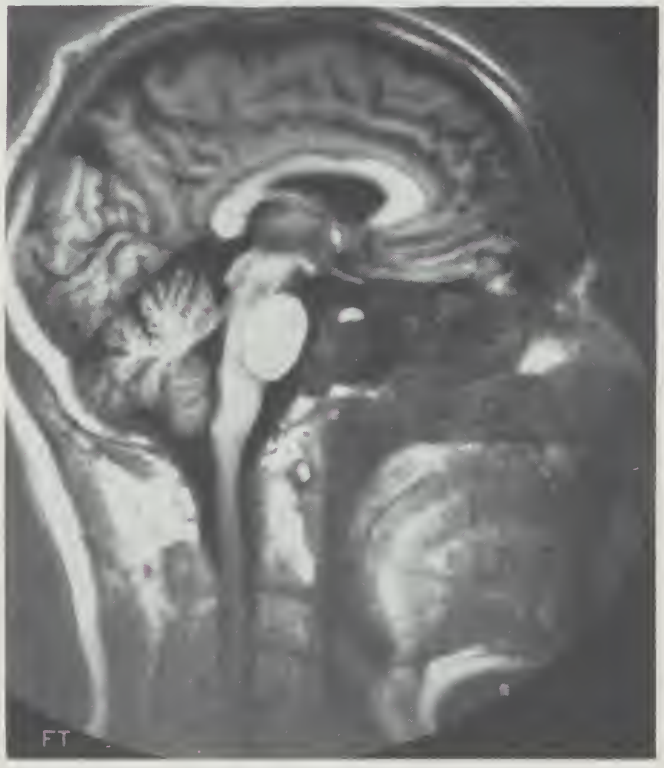


Figure 1. Normal midline sagittal MR scan of the brain.

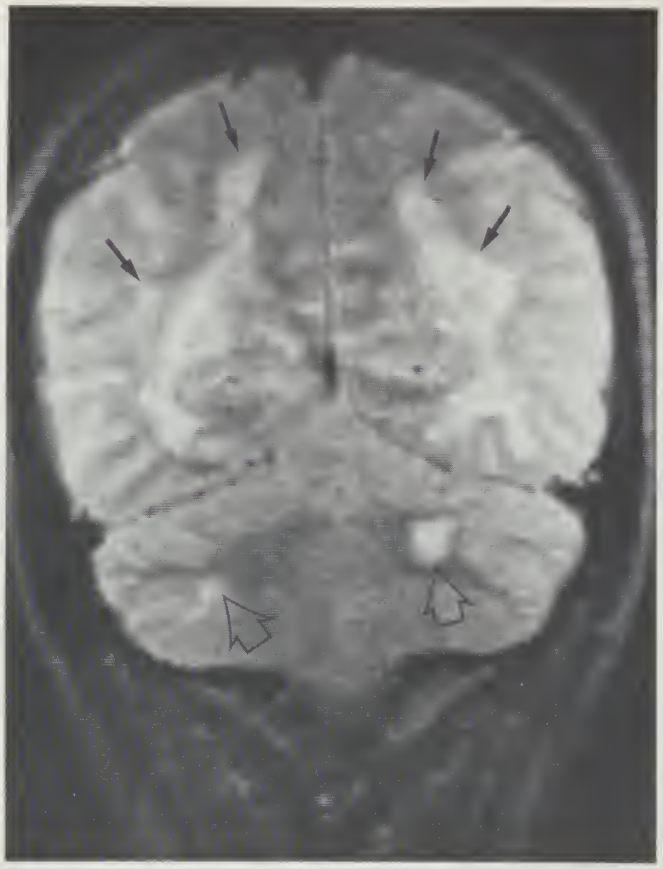


Figure 2. Coronal image. Multiple sclerosis. Abnormal areas of high intensity (bright) in the cerebral periventricular white matter (arrows). Focal areas in the cerebellum (open arrows).

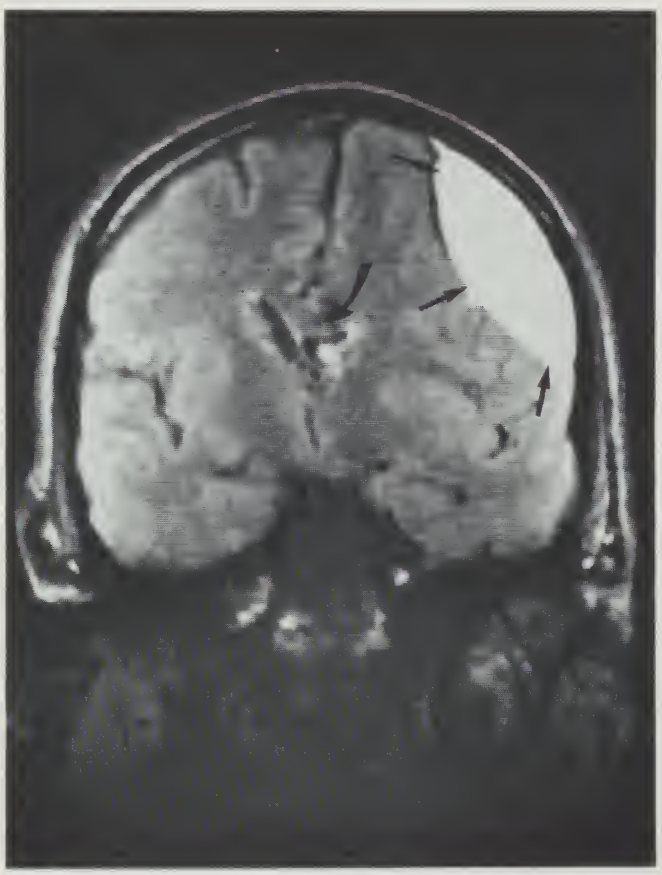


Figure 3. Coronal image. Subdural hematoma (straight arrows). Note the subfalcine herniation (curved arrow).

frequent detection of metastases, multiple sclerosis plaques (Figure 2), and other demyelinating diseases; and earlier and more frequent detection of infarcts and edema.[2-5] In a comparative evaluation of MR and CT in patients with temporal lobe epilepsy, MR found temporal lobe abnormalities in twice as many patients as did CT.[6]

With CT, acute hemorrhages usually have increased attenuation coefficients. However, the blood sometimes becomes isodense with the brain, resulting in decreased attenuation coefficients. On MR, with different pulse sequences, blood can be seen in all of its phases, even when isodense with the brain on the CT scan (Figure 3). Hemorrhage can be distinguished more easily from calcification than on CT since hemorrhage has a high intensity on T2-weighted images and calcification has a low intensity on both T1- and T2-weighted images. Nevertheless, CT is the preferred method in the evaluation of acute hemorrhage. Rapidly flowing blood, aneurysms, and arteriovenous malformations give a decreased signal on both T1- and T2-weighted images (Figure 4).

With respect to differential diagnosis of intracranial lesions, MR so far has not lived up to the most enthusiastic early predictions that measurement of T1 and T2 would permit improved or specific *in vivo* characterization, such as differentiation of benign from malignant tumors and tumors from inflammatory processes, infarction, demyelination, and certain degenerative diseases. Most tumors have prolonged T1 and T2 tissue characteristics. The only lesions that have been shown to cause shortened T1 are nonacute hemorrhage, lipid-containing tumors, and some melanotic tumors.[7] Although CT is less sensitive, MR and CT probably have equal specificity for differentiating lesions. There is hope, however, that further experience with MR will yield more specific techniques. Paramagnetic materials are being developed as injectable MR contrast agents and will be able to enhance lesion contrast and increase the specificity of MR.

MR of the spine and spinal cord has been particularly advantageous. Imaging in the sagittal plane allows long segments of the spine and cord to be included in one image, whereas with CT, numerous thin transverse sections must be obtained. Very high contrast can be achieved between the spinal cord and cerebrospinal fluid, obviating the need for myelography in many cases. MR has been shown to be highly effective in the demonstration of syringomyelia (Figure 5), Arnold-Chiari malformation (Figure 6), spinal cord tumor, and cord atrophy.[8] MR is capable of differentiating the intervertebral disc nucleus pulposus from the anulus fibrosus and determining nucleus pulposus desiccation before anatomical changes have occurred. Herniation of disc



Figure 4. Coronal image. Primarily infratentorial AVM extending through tentorial incisura (arrows). Aneurysm (arrowheads).



Figure 5. Sagittal image. Post-traumatic syringomyelia of the spinal cord extending from C7 to T2-3 (long arrows). Slight subluxation (short arrow).

contents can be revealed by MR, but CT is preferred for study of routine invertebral disc herniation. MR has become the most sensitive and specific method for evaluation of disc space infections, a difficult diagnosis using CT.[9]

The Future

There is growing experience with MR in areas of the body outside the neural axis. MR shows promise for evaluation of hepatic, splenic, and renal abnormalities but is still too inconsistent to challenge CT or ultrasound as the imaging method of choice. Respiratory motion leads to severe degradation of image quality in some patients. The use of respiratory gating results in high quality images but at the expense of increased examination time. MRI with cardiac gating and combined cardiac and respiratory gating is being used to study the cardiovascular system. The four chambers of the heart are easily separated from one another by the well-defined myocardial segments, which appear gray, and the cardiac valves, which appear as linear white densities. MR's ability to obtain data directly in the axial, coronal, or sagittal planes is an advantage over other cardiac imaging models.[10] The vertical orientation of viscera and vessels within the mediastinum is ideally suited to imaging in the coronal and sagittal planes. Mediastinal and pulmonary hilar masses can be distinguished easily from blood vessels by virtue of the absence of signal from flowing blood.[11] MR characteristics of cardiovascular abnormalities such as intimal flaps, atheromatous plaque, wall thickening, and luminal stenosis in large- and medium-sized blood vessels appear



Figure 6. Sagittal image. Arnold-Chiari malformation type II. Note elongated mesencephalon and herniation through foramen magnum (curved arrows), compression of the fourth ventricle (small arrows), and hydrocephalus (long arrows).

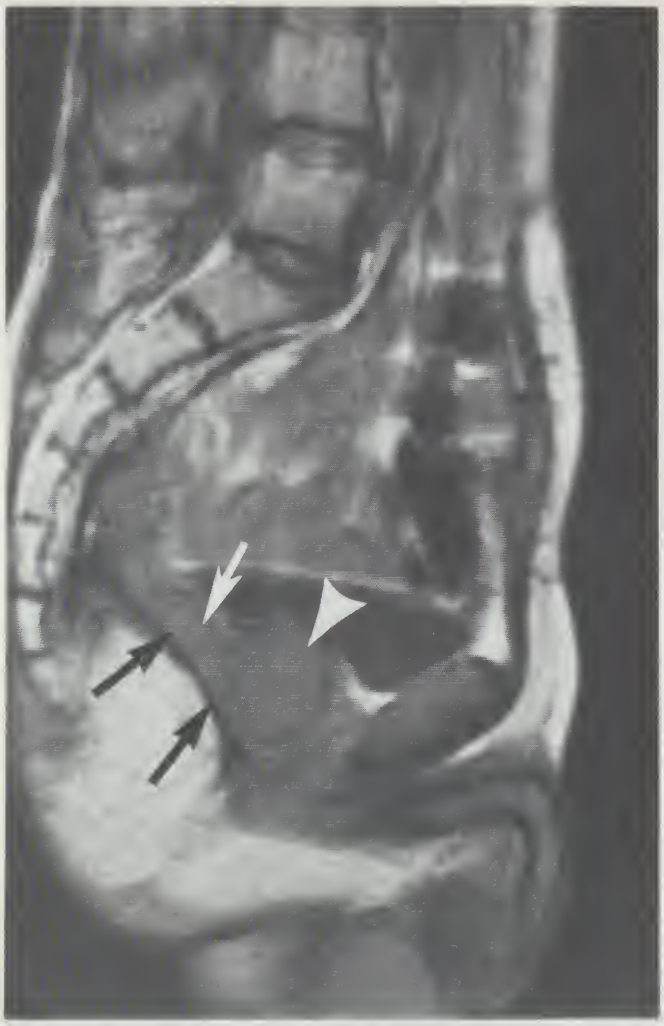


Figure 7. Sagittal image. Recurrent rectal carcinoma (arrows). Enlarged prostate (arrowhead). Rectum has been removed.

clearly, but prospective comparison with other methods will be necessary before the role of MR in vascular disease is known.[12]

The pelvis is one area where MR seems best suited and needed (Figure 7). Pelvic structures are not affected by respiratory motion and are appropriate for imaging in the coronal and sagittal planes. CT and ultrasound are valuable but have been ineffective in staging pelvic tumors. In addition to the detection of pelvic lymphadenopathy, MR's superiority in showing tissue contrast has enabled detection of prostatic tumors confined to the gland as well as extraglandular disease.[13,14] Prospective clinical trials are under way to validate whether MR imaging can differentiate pelvic neoplasms localized to organs from those that have infiltrated surrounding pelvic fat or extended to the pelvic walls and lymph nodes.

In the short time MRI has been clinically available, it has affirmed its role in neurodiagnosis, becoming the method of choice for the evaluation of many neurological problems. Yet it is unlikely that MR will totally displace other imaging techniques. For some clinical problems it will replace x-ray, CT, or myelography, and for others it will replace nuclear medicine imaging and sonography.

The primary advantage of MR is its multidimensional display and superior sensitivity for the detection of brain and spinal abnormalities. We believe that the enhanced ability to detect disease while replacing more invasive tests will prove cost-effective and safer for the patient.

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Osteoarthritis X: Cervical Spondylosis

CAROL M. ZIMINSKI MD

Pain in the neck, shoulder, or arm, sometimes associated with upper limb disability, is a frequent complaint of patients seeking medical attention. The cause of the symptoms may be obvious, such as trauma, or it may be more obscure. One of the most common causes of pain and disability in the neck is osteoarthritis of the cervical spine (cervical spondylosis). This article reviews the etiology of cervical spondylosis, the radiographic and clinical features, and principles of management.

Dr. Ziminski is an Instructor in Medicine, The Johns Hopkins University School of Medicine, Baltimore, MD.

The neck is the most mobile segment of the spine. Through this cylinder connecting the head to the thorax pass structures requiring the greatest protection and having the least: the carotid and vertebral arteries, the spinal cord, and the spinal nerves. The head, weighing six to eight pounds, is perched on top of the seven cervical vertebrae in a flexible chain held together by 14 apophyseal joints, 5 intervertebral discs, 12 joints of Luschka, and a system of ligaments and muscles allowing maneuverability and range of motion, designed for mobility at the expense of stability.

Normal function of the cervical spine requires physiologic movements of the joints, bones, spinal cord, nerve roots through the intervertebral foramina, muscles, ligaments, tendons, fascia, sympathetic nervous system, and requires also the intact vascular supply of all these structures. Since most structures in the neck may become pain sensitive, a knowledge of the dermatome pattern of pain distribution is necessary in clinical diagnosis. Differentiation is required to identify and separate neural, vascular, muscular, ligamentous, joint, and bone pain; spinal cord and peripheral nerve pain need specific recognition.

Cervical spondylosis is the most common disorder of the cervical spine. Most patients have osteoarthritis elsewhere, frequently asymptomatic. Cervical spondylosis is osteoarthritis of the cervical spine, which may occur at several intervertebral articulations: the amphidiarthrodial joints (intervertebral discs), apophyseal joints, and uncovertebral joints (Luschka). An understanding of the clinical syndromes of cervical spondylosis requires that the process in each of these segments be understood.

Etiology

Osteoarthritic changes may occur within and around the intervertebral disc. Aging or degeneration related to chronic trauma distorts the arrangement of fibers in the annulus fibrosus, the constraining fibrous ring surrounding the intervertebral discs. The disc itself develops abnormal structural changes: clefts, scarring, neovascularization, and resiliency, the property that enables the disc to function as a shock absorber, decreases. These changes in the spine's flexibility and resilience alter the spine's ability to respond to stress and lead to the development of osteophytes around the body of the vertebra and to disc space narrowing. The osteophytes that form may encroach on the neural foramina, through which the nerve roots exit from the spinal cord. In addition, in the cervical spine, osteophytes may encroach on the foramina through which the vertebral artery passes.

Osteoarthritis of the spine also can occur at the apophyseal facet joints. The pathologic changes are similar to those that occur at the diarthrodial joints of the limb and include joint space narrowing, cyst formation, sclerosis, and osteophyte formation. In the cervical spine, the uncovertebral joints (joints of Luschka, apophyseal joints located on the posterolateral surface of the vertebral bodies) also can become osteoarthritic.

Multiple vertebral levels usually are altered, and changes predominate in the lower cervical spine. The most commonly involved site is the intervertebral disc at the C5-C6 level, followed by the C6-C7 level. The intervertebral disc at the C2-C3 level is least often affected. Osteoarthritis of the apophyseal articulations also is most common in the middle and lower cervical spine. Associated changes in the joints of Luschka show a predilection for these same levels, particularly the C5-C6 intervertebral disc space.

There is a high incidence of cervical spondylosis in the second half of life, increasing in severity with advancing age and becoming almost universal beyond age 70. Cervical spondylosis is commonly silent and asymptomatic, that is, with varying radiographic evidence from mild to severe without subjective symptoms or objective signs referable to the neck. Past episodes of pain, stiffness, or paresthesia may be elicited.

Radiographic Features

The most obvious findings are alterations in the curvature of the spine, with straightening or reversal of the normal cervical lordosis, which may be related to muscle spasm. Narrowing of the intervertebral disc spaces (particularly C4 through C7) with anterior and posterior osteophytes is common. Osteophytes may be noted on the uncovertebral joints (Luschka), or may be

laterally situated on the vertebral bodies. Osteophytes on the uncovertebral and apophyseal joints, or on the vertebrae themselves, may encroach on the intervertebral foramina. The vertebral bodies may be deformed. There may be sagittal diameter narrowing with resulting cord compression.

Attempts have been made to correlate radiographic changes of cervical spine degeneration with clinical symptoms and signs. In a large group of asymptomatic patients, 25 percent of patients in the fifth decade of life and 75 percent of patients in the seventh decade of life had radiographic changes, attesting to the fact that exuberant osteophytosis need not be associated with significant clinical manifestations. In both symptomatic and asymptomatic groups, abnormalities were noted most frequently at the C5-C7 levels.

In patients over the age of 50 who enter the hospital for reasons unrelated to the spine or nervous system, 75 percent may have significant radiologic evidence of cervical spondylosis. Pallis *et al.* found 75 percent with narrowing of the intervertebral foramina caused by uncovertebral and apophyseal joint osteophytes; 50 percent with objective physical signs of cord involvement; 40 percent with signs of root involvement; and 60 percent with abnormalities of the neck on physical examination. Signs included impaired vibration sense at the ankle, brisk knee and ankle jerk, or positive Babinski responses. Few had any complaint.

These findings indicate that considerable caution must be applied to the interpretation of the clinical significance of observed radiographic abnormalities, and that radiologic changes alone should not be used as a guide in determining the necessity of surgical intervention.

Clinical Features

The symptoms and signs associated with cervical spondylosis reflect the location and extent of the disease; these include stiffness, limitation of movement, crepitus, local pain and tenderness, and considerable muscle spasm. The symptoms may be accentuated or made noticeable by minor trauma.

Chronic aching pain may be localized to the neck or may radiate. Upper cervical disc pain may be perceived in the head and upper neck; lower disc pain may be felt lower in the neck and into the shoulders and proximal arm, forearm, and hand. The pain is usually worse with movement, particularly extension of the neck or lateral flexion to the side of pain. Motion is limited (lateral flexion, rotation, and extension more so than forward flexion), and the head may be held in a tilted position, presumably due to protective muscle spasm. The site and mechanism of pain may be ligamentous, tendinous, or capsular. Many patients, especially in a late stage of this disease, have little or no neck pain but only symptoms of nerve root compression.

Radiculopathy If a cervical nerve root is encroached on by osteophytes or synovitis of an apophyseal joint, symptoms of a peripheral neuropathy may occur. Root involvement may be single or multiple, unilateral or bilateral, symmetrical or asymmetrical. There is no predictable pattern. Both the sensory and motor roots may be involved, with symptoms of irritation or paralysis or both. Autonomic involvement is common. Sensory symptoms are more common and more prominent than motor symptoms; they include pain, paresthesia, hypoesthesia and hyperesthesia. Pain may be referred to the head, neck, scapula, suprascapular or humeroscapular region, chest wall, deltoid, arm, forearm, hand, and fingers. The "neuralgic" pain from the posterior root is severe, intermittent, shooting, stabbing, referred via dermatome or scleratome. It reaches its greatest intensity at the periphery. "Myalgic" pain is referred via the appropriate myotome. It is proximal pain, continuous, with a deep, piercing quality, and may be associated with deep muscle tenderness in the neck, shoulder, and arm.

Involvement of the C6 nerve root is characterized by pain and sensory deficit over the radial aspect of the forearm, thumb, and index finger. These symptoms may be associated with weakness and atrophy of the biceps muscle and decrease in the biceps reflex.

Patients with C7 radiculopathy have pain and sensory deficit over the dorsum of the forearm, wrist, and index and middle fingers. There may be weakness and atrophy of the triceps muscle and diminution of the triceps reflex.

Paresthesias Nerve root pains are generally proximal, rarely extending below the elbow, whereas paresthesias are frequently distal. Paresthesias may be described as "pins and needles," "going to sleep," hot or cold sensation, numbness, clumsiness, or reduced dexterity.

Myalgias Muscles may be tender in areas around the neck, shoulder girdle, or arm. Such areas of focal tenderness represent local muscle spasm. Local anesthetic injection may provide long periods of symptomatic relief.

Sensorimotor Changes Objective sensory loss is unusual despite frequent sensory symptoms. Such symptoms may be aggravated by neck movements and may be reproducible with flexion, extension, rotation, lateral flexion, or axial compression of the neck. Lower motor neuron changes may be evident, with weakness, atrophy, hypotonic muscles, and, early on, fasciculations. Muscles are innervated by more than one nerve root; thus, extensive paralysis occurs only when multiple roots are involved. Diminution or absence of reflexes

is the most common single objective sign of cervical spondylosis.

Autonomic disturbances seem more likely due to secondary scalene muscle spasm than to primary autonomic involvement. Such spasm might compress brachial plexus sympathetic fibers, mediating vasospastic phenomena in the arm: blanching, cyanosis, flushing, altered temperature, or swelling and edema of the hand, a reflex sympathetic dystrophy syndrome.

Myelopathy It is possible to have a significant midline protrusion in the cervical area that causes a myelopathy with long tract signs and bladder problems. The myelopathy of cervical spondylosis is the most common disease of the spinal cord after middle age and may indeed be the true cause of such syndromes as "idiopathic" primary lateral sclerosis or progressive paraplegia of middle life. The onset is insidious, and diagnosis may be made only after several years, if then. Onset may be acute as trauma or an obstructive vascular lesion. The neurological symptoms and signs are variable and difficult to classify, since they depend on the nature and number of lesions, site, rate of evolution, and extent—factors that are variable and unpredictable. In general the symptoms and signs can be grouped into local (cervicobrachial and cervicocephalic) or those referred to distal parts.

Motor changes predominate in the lower extremities, including spastic paraparesis, decreased strength (particularly flexors), hyperreflexia of knee and ankle jerks with clonus, extensor hypertonia, and positive Babinski sign. In the arms the deep tendon reflexes may be increased, decreased, or absent. With abnormal upper extremity reflexes there is an increase in ipsilateral reflexes at knee and ankle. The jaw jerk is generally normal.

Sensory changes are most marked in the upper extremities. Patients may experience a sense of pain, heat, or cold and may have objective evidence of loss of pain, heat, or cold sensation. Vibratory sense, proprioception, or position sense may be diminished or absent. Numbness or paresthesia may be prominent.

Autonomic visceral changes are uncommon. However, bladder symptoms (including urgency, frequency, hesitancy, retention, and incontinence) are common. Combined radiculopathy and myelopathy are common, as well as occasional vertebrobasilar insufficiency with either or both.

The differential diagnosis may be very simple or quite difficult, because cervical spondylosis is such a common and frequently asymptomatic occurrence in the aging spine. Evidence of neurological dysfunction above the neck casts doubt on spondylosis as a cause, for example, positive jaw jerk. Differential considerations include soft disc protrusion, intracranial or spinal cord tumors, multiple sclerosis, subacute combined degeneration of the cord, peripheral neuropathy, motor neuron disease, cerebellar disease, syringomyelia, tabes dorsalis, and hysteria.

Vertebral Artery Insufficiency The symptoms of vascular compromise are as various as the functions of the structures rendered ischemic. Turning the head may induce the symptoms, often reproducibly but not without danger. Rotation of the neck to one side even in normal circumstances may decrease the blood flow in the atlantoaxial portion of the vertebral artery on the ipsilateral side. Depending on the adequacy of the carotid circulation, ischemia may or may not develop. Many factors influence blood flow in the vertebral and carotid circulation, including usual and unusual neck movements, atheromatosis, cholesterol emboli from plaques, congenital anomalies, carotid sinus compression, trauma, surgical collars, and disorders of bone, joint, and muscle in the cervical spine. Compromise of the vertebrobasilar circulation may result in transient ischemic attacks or permanent infarction, with loss of function in the territory of the vessel involved.

Differential Diagnosis Many clinical conditions arising outside the cervical spine are perceived in or about the neck area and may mimic cervical root irritation, muscle spasm, ligament strain, bone disease, and joint disorders. Pain caused by irritation of the cervical nerve roots must be differentiated from the following: pain reflexly referred from somatic and visceral structures that have the same segmental nerve supply; pain resulting from involvement of a nerve or its branches; pain caused by lesions of the spinal cord and of the brain; and pain of psychogenic origin.

Differentiation is based on certain neurologic considerations. Pain from nerve root or nerve trunk irritation is referred to various points along the segmental distribution of that root or trunk. At the sites of pain, deep tenderness and muscle spasm are found. Irritation of a nerve causes pain referred proximal or distal to the site of involvement, but the painful areas are not tender to deep palpation. Pain that originates in a somatic or visceral structure may be referred along the segmental distribution of the nerve supply of such structures, but these areas of pain are not tender on deep palpation, although hyperesthesia may be present. Areas of superficial peripheral tenderness may be associated with reflex or direct sympathetic irritation secondary to vasomotor changes. Referred painful areas have no associated muscle spasm, and often will be described as having a burning or cramping sensation. Spinal cord tumor or an intracranial lesion produces a poorly localized and ill-defined neck pain; hyperreflexia, hypertonia, or spasticity may be present. Deep tenderness and local muscle spasm are absent, and the pain is not

relieved by immobilization. In addition, spinal cord lesions may produce paralysis or weakness below the cord level, associated with sensory changes and Babinski signs.

Skilled elicitation of historical data and careful attention to the physical exam remain the principal and most reproducible means of making a differential diagnosis. Additional information may be provided by radiographs, electrodiagnostic studies, CT scans or myelography where appropriate, or even arteriography if vertebral artery insufficiency is suspected.

Management

Cautious clinical, electrodiagnostic, and radiographic assessment, to exclude other causes of pain in the neck and upper limb, must precede the planning of treatment. Management of cervical spondylosis is guided by: (1) the age and occupation of the patient, (2) the severity and duration of symptoms, (3) the presence or absence of neurologic findings, and (4) the severity of the condition as demonstrated by electrodiagnostic and radiographic evaluation (which may include CT scan and myelography).

Bed Rest Medical therapy aims at the relief of pain and stiffness in the neck and arms. Bed rest should be reserved for acute cases, for chronic cases with an acute exacerbation of symptoms, or for patients in whom ambulatory treatment fails. For the relief of pain, adequate analgesics should be prescribed. Full therapeutic doses of salicylates or other anti-inflammatory and analgesic medications usually suffice. Muscle relaxant drugs, hypnotics, or diazepam may be used concomitantly. With complete bed rest and sufficient analgesic, anti-inflammatory, and muscle relaxant medications, acute neck pain usually subsides within seven to ten days. When acute pain resolves, the patient begins active exercises.

Cervical Collar In cervical spondylosis and other musculoskeletal syndromes, limitation of neck movement benefits the patient, and cervical collars can be used to achieve this end. Patients with nerve root pain often experience symptomatic relief after wearing a collar. Patients with generalized spondylosis do less well than those with focal spondylosis. It is essential to assess the degree of disability, and the type of collar selected should depend on the degree of immobilization desired. Felt, foam, and rubber collars restrict gross movement, while plastic and plaster collars give more secure immobilization. Any collar must fit well and maintain the neck in the most comfortable position. In general, the patient should leave the collar off after about two months to prevent weakness and wasting of the neck muscles. After the acute painful stage subsides, active exercise in conjunction with collar use should be encouraged.

Traction Traction, properly and safely done, can be a mainstay of management. Traction may be continuous or intermittent, mechanical or manual. Continuous traction should be reserved for more severe cases with symptoms of nerve root compression. Many patients cannot tolerate traction, and a few will become worse with it. Analgesics and muscle relaxants can be used in doses sufficient to prevent restlessness. Traction appears unsuitable for patients with visible gross x-ray changes of the cervical spine, because of the danger of spinal cord compression or pressure on the vertebral arteries.

Exercises Active exercises should be included in most treatment regimens. Types of exercises are

1. anterior-neck mobilizing
2. shoulder raising
3. muscle strengthening

Shoulder exercises, designed to elevate the shoulder girdle and relieve the drag on nerve roots, can be combined with use of a cervical collar.

Other Measures In the acute situation, ice applied to painful areas often may relieve symptoms. Heat in all forms, particularly moist heat, is almost uniformly beneficial, probably because it relieves muscle spasms.

Surgery Surgical intervention may be appropriate in two groups of patients. One group has symptoms that relate principally to the nerve roots emerging from the cervical spine, and the condition presents itself with either neck or arm pain. In a different group, a slowly progressive spinal cord syndrome may develop, involving first the legs and then the arms.

Patient Education An important aspect in the treatment of patients with cervical spondylosis is patient education. The clinician should define the problem to the patients' understanding, instruct them in the rationale of treatment, and teach them how to care for their necks in standing, sitting, driving, and other activities of daily living.

Summary

Osteoarthritis of the cervical spine is common, and is almost universal after the age of 70. Cervical spondylosis may be silent and asymptomatic, or it may cause a variety of clinical syndromes. Care must be taken to exclude other processes, such as tumor, neuropathy or myopathy from other causes, vascular insufficiency, or other mechanical derangement. In general, conservative management, including analgesics, muscle relaxants, soft collar, exercises, and physical therapy will be successful in alleviating symptoms in the majority of patients.

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Atypical Lyme Disease or *Forme Fruste*

VINCENT L. GUANDOLO MD

The patient presented a clinical picture of a distinctive skin lesion, transient oligoarticular arthritis, and symptoms of meningoencephalitis that suggested Lyme disease or a syndrome compatible with this illness. The puzzling aspect of the case was that the presumed vector was not a tick, as usually reported, but a flying arthropod.

Presented at Grand Rounds, Children's Hospital National Medical Center, Washington, DC, April 23, 1984. Dr. Guandolo is Associate Clinical Professor of Child Health and Development, Department of Pediatric Medicine, Children's Hospital National Medical Center, Washington, DC. He is in private pediatric practice, 19251 Montgomery Village Avenue, Gaithersburg, MD 20879-2081.

A 13 year old girl who has had diabetes mellitus for 10 years presented with a four-day history of right knee pain and swelling aggravated by movement. There was no history of trauma or previous febrile illness. For approximately three weeks prior to the onset of knee pain the patient was bothered by fatigue, lethargy, and severe headaches. These symptoms prompted frequent checks on her diabetic status and repeated use of acetamenophen to relieve the headaches.

The physical examination was normal except for a warm, mildly swollen, nonerythematous right knee and a large, red, targetlike lesion of the inner aspect of the left thigh. Attention was drawn to the skin lesion and details were sought to clarify the finding.

On Labor Day weekend (one month prior to the office visit) the girl was hiking in Maryland's Catoctin Mountains (Cunningham Falls) and was bitten on her exposed left thigh by a "skinny, black, flying bug." The insect was aggressive and attempted a second attack before being shooed away by the patient's father. The parents claim it was not a bee or wasp.

The site of the bite was initially pale, painful, and pruritic. Within 20 minutes the site changed to a round, red patch; the erythematous macule gradually expanded in a circular fashion during the first 48 hours to form a large annular lesion 8 cm in diameter. Oral antihistamines did not affect the progress. The round lesion continued to expand centrifugally and reached its largest diameter (10 cm) by the third day following the bite. Development of an enlarging erythematous and indurated area within the annular lesion and immediately around the prominent central puncture site prompted the patient to seek emergency medical care.

At the emergency center a diagnosis of staph cellulitis was made and oral cephalosporin was prescribed. Two days later there was partial central clearing of the lesion. Thirty days after the bite the large, round skin lesion measured 10 cm and had an erythematous, mildly indurated, raised circumference, an area of clearing within this ring lesion, and a persistent, red, indurated central prominence. Laboratory tests for inflammatory and rheumatoid disease were normal. A subsequent ECG was normal. Penicillin 250 mgm qid was prescribed for ten days.

The initial knee pain subsided in three days but recurred for short periods on at least three occasions over the next two months. The skin lesion faded slowly. The patient continued to complain of recurrent and transient annoying problems such as: lethargy, headache, low-grade fevers, nausea without vomiting, inability to hold a pencil while trying to write, left knee pain aggravated by exercise, low back and abdominal pains, and a recurrent, evanescent, morbilliform rash of the neck and upper chest. The annular skin lesion became more prominent when the patient bathed or became overheated. The patient's daily insulin requirement increased by 5 units during that two month period.

Ninety days following the bite the patient was free of symptoms and has remained so to the present. Only a small, red papule remained at the site of the bite. Insulin requirements decreased.

Lyme Disease

The persistent efforts of a concerned mother sparked the investigation of Lyme disease. Mrs. Mensch, a former resident of Old Lyme, Connecticut, refused to accept a diagnosis of juvenile rheumatoid arthritis in her daughter. Her perseverance eventually led her to Dr. Allan C. Steere of Yale University. In 1975–76 Dr. Steere and investigators from Yale discovered a clustering of cases of an unusual form of arthritis in the three communities of East Haddam, Lyme, and Old Lyme, Connecticut. The illness affected adults and children in the summer months. It was more common along sparsely populated roads than in town centers, and thirty times more frequent on the east side of the Connecticut River than on the west. This condition was given the name "Lyme arthritis."

Geographic Distribution

Since 1977 an estimated 3,000 cases of Lyme disease have occurred in the United States making this disease one of the most common tick-borne ailments to affect man. States (other than those in known endemic areas) reporting cases of Lyme disease are New Jersey, North Carolina, Texas, Arkansas, Delaware, Florida, Virginia, Iowa, and Georgia. The state health department of Maryland has 18 cases of Lyme disease on record since 1979; almost half of these were detected in Cecil County

on Maryland's eastern shore. Lyme disease also has been reported in Scandinavia and Australia.

The identification of Lyme arthritis led to investigation of other manifestations associated with the joint findings. In about 1980 these studies resulted in a description encompassing the clinical spectrum of Lyme disease. Primary body areas affected by the multisystem, immune-mediated, inflammatory disorder are the skin, joints, nervous system, and heart.

Another significant finding was the seasonal acquisition of the illness (between May and November with 80 percent of cases in June and July). The summer clustering suggested a tick or other arthropod as possible vector. That theory was supported by the histopathology of the skin lesion.

There is no predictable progression or pattern to the chronology of Lyme disease. Signs and symptoms overlap and recur. Arthritis can develop subsequent to or before neurologic or cardiac findings. Lyme disease potentially can present as an isolated cutaneous, neurologic, arthritic, or cardiac episode. However, of the cases surveyed by Schrock in 1982, over 90 percent first came to medical attention with skin and/or joint manifestations. Cardiac involvement has not been reported as a finding on initial presentation.

Early signs and symptoms are nonspecific and can suggest a viral syndrome. However, unlike viral illness the most characteristic feature of Lyme disease is that the clinical condition rarely is static. There are frequent, rapid, and transient changes in the patient's status.

Skin The characteristic skin lesion is called erythema chronicum migrans (ECM) and has been referred to as the best clinical marker for Lyme disease. Some consider it pathognomonic for Lyme disease. ECM has been characterized as a red papule or macule that expands to form a large, round (or annular) lesion with an indurated border and central clearing radiating from the site of a prior arthropod bite. 85 percent of patients with Lyme disease have ECM. ECMs can occur anywhere on the skin; common sites are thigh, axilla, and groin.

From a historical perspective the relationship between tick bites and ECM first was established in 1909 by Swedish physician Arvid Afzelius. The disease was known as "erythema chronicum migrans Afzelius." Scrimenti reported the first case of ECM in the United States from Wisconsin. Scrimenti's patient also had associated neurological signs and right hip pain. The administration of Bicillin reportedly was curative in 48 hours.

Single ECM lesions have been reported as large as 50 cm in diameter. The lesion usually conforms to the contour of the affected body area. Scalp lesions may appear as a red, linear streak at the hairline. ECM may be warm to the touch. Some patients have described sensations of pain, burning, and itching of the lesion.

Multiple secondary lesions appear in roughly half the patients with skin manifestations of Lyme disease. These lesions usually have no central red, indurated area, are smaller, and expand or migrate less than the original ECM. Some secondary lesions may have a central bluish hue reminiscent of erythema multiforme except they do not involve the palms, soles, or mucous membranes. Approximately 13 percent of patients with secondary lesions may have 30 to 40 such eruptions. Two patients were reported to have over 100 annular secondary lesions.

A more chronic form of ECM may appear as a large, dry, scaling numular patch. Other skin manifestations of Lyme disease include urticarial rashes, evanescent red circles, or blotches.

Joints Approximately half the patients with Lyme disease develop acute asymmetric arthritis. Lyme arthritis is defined as (1) brief but recurrent attacks of asymmetric oligoarticular swelling and pain, primarily in large joints, or (2) periods of migratory polyarthritis in both large and small joints. Early attacks are short-lived, averaging about seven days in duration. Periods of complete remission are present between attacks. The average number of recurrent attacks is three. Recurrences of arthritis are not necessarily in the same joint. Involved joints are warm and swollen but without erythema.

First attacks in children usually are monoarticular. The knee joint is involved in more than 80 percent of Lyme arthritis cases on both initial and recurrent attacks. The involved joint is not necessarily the one closest to the site of the skin lesion.

Approximately 10 percent of patients with Lyme arthritis may develop a chronic arthritis problem pathologically similar to rheumatoid arthritis. All chronic problems reported have involved the knee joint. Chronic involvement can start anywhere from 4 to 24 months following bouts of Lyme arthritis and persists for at least 9 to 12 months. The B-cell allo-antigen found in most patients with chronic Lyme arthritis (DRw2) is different from either ankylosing spondilitis or rheumatoid arthritis. Chronic Lyme arthritis has no related morning stiffness, sub-q nodules, urethral, or eye complications.

Nerves 11 percent of patients with Lyme disease have neurological involvement. The spectrum of neurological problems demonstrates diffuse involvement of both central and peripheral nerves. One author char-

acterized the neurological involvement as "fluctuating meningoencephalitis with superimposed cranial and peripheral neuropathy or radiculopathy." There have been reports of myelitis and two suspected cases of hemiparesis.

The common first indication of neurological involvement in Lyme disease has been severe headache and stiff neck. Signs and symptoms can present from four to sixty days following the onset of the illness. The prognosis generally is favorable with the majority of patients recovering in about three weeks. However, there is a wide variant of resolution of neurological manifestations (from two weeks to eight months).

In patients with evidence of encephalitis EEGs have shown a pattern of nonspecific slowing; CAT scans, isotope brain scans, and skull x-rays have been normal.

The variety and overlapping propensity of neurological findings in one series of 18 patients showed the following breakdown:

1. Meningitis (75 percent)—headache, stiff neck, photophobia, nausea, and vomiting.
2. Encephalitis (67 percent)—somnolence, lethargy, emotional lability, depression, poor memory and concentration, and behavioral changes.
3. Cranial neuritis (55 percent)—primarily unilateral facial nerve (Bell's) palsy; other cranial nerves involved: sensory component of trigeminal, occulomotor, abducens, and auditory.
4. Radiculoneuritis or inflammation of the nerve root and nerve (44 percent):
   a. Motor (50 percent)—usually the shoulder girdle
   b. Sensory (40 percent)—cutaneous hyperesthesias to touch and temperature
   c. Motor and sensory (10 percent)
5. Myelitis or inflammation of spinal cord (5 percent)—loss of rectal sensation, impotence, and positive Babinski signs.

The usual spinal fluid finding has been a lymphocytic pleocytosis. Examination of cerebrospinal fluid early in the disease may result in normal values.

The relationship between tick bites and neurological abnormalities dates back to the 1920s. In Europe a disease long known as tick-borne meningopolyneuritis (*Garin-Bujadoux, Bannwarth*) has clinical findings similar to the neurological picture of Lyme disease.

Heart 8 percent of patients with Lyme disease have cardiac involvement. Variable heart block secondary to atrioventricular conduction defects are the most common cardiac problems.

Cardiac signs and symptoms, like neurological abnormalities, tend to fluctuate from one stage to another. The usual onset of cardiac involvement is one to six weeks following skin or joint signs. Duration of cardiac problems is about one week but has been recorded as long as three to six weeks. Electrocardiographic changes are consistent with myopericarditis. Unlike rheumatic heart disease, there is no valvular involvement.

Common symptoms of significant cardiac involvement with Lyme disease are syncope, dizziness, shortness of breath, substernal pain, palpitations, or sensation of choking or drowning. The clinical sign of heart abnormality is either tachycardia or bradycardia. In cases of complete heart block, transvenous pacemakers may be required. Single cases of pericardial friction rub, pericardial effusion, and cardiomegaly with pulmonary hypertension have been reported.

Vector

Ticks come in two varieties: hard and soft shell. The hard-shell ticks of the *Ixodidae* family are prime vectors of disease in man.

The species *dammini* was described first by Dr. Andrew Spielman of Harvard in 1979. The species was named in honor of Gustave Dammin, pathologist at the Peter Bent Brigham Hospital, in recognition of his support of Dr. Spielman's research.

The *Ixodes dammini* tick is small; the adult measures 2 mm in the unengorged state. Immature ticks are smaller, pale in color, and frequently difficult to detect. *I. dammini* ticks have been implicated as the vector of Lyme disease in various parts of the northeast and midwest. *Ixodes pacificus* ticks are found in the far west and have been incriminated as vectors of Lyme disease in that area.

The life cycle of the tick is approximately two years and consists of four stages: egg, larva, nymph, and adult. Eggs are deposited on the ground, and larvae and nymphs aggressively seek small rodents to parasitize. Larvae can acquire the infectious agent by transovarial passage. These immature ticks feed on many animal species; thus the potential for growth and spread of an infectious organism is great. Larvae, particularly the nymph stage of *Ixodes dammini*, can transmit the infectious agent of Lyme disease. Dogs and cats in endemic areas have been found to be carriers of these ticks.

Adult ticks prefer larger animals such as the white-tailed deer. These deer are considered to be the reservoir for Lyme disease and provide overwintering for ticks and the infectious agent.

Causative Agent

In 1948 Lenhoff reported finding spirochetes in ECM, erythema multiforme, pityriasis rosea, psoriasis, and seborrhea. Other investigators could not confirm these

findings. However, some physicians accepted Lenhoff's results and used antispirochetal medications such as bismuth and penicillin to treat ECM. Reports of that treatment, especially with penicillin, were favorable.

In 1982 Burgdorfer reported isolation of a treponemalike spirochete from the intestinal tract of adult *I. dammini* ticks. These infected ticks were shown to cause typical ECM lesion on the skin of rabbits. Patients recovering from Lyme disease were found to have antibodies to the *I. dammini* spirochete. Later nymphal ticks, small and large rodents, and white-tailed deer also were shown to harbor the *I. dammini* spirochete.

In 1983 Steere and associates isolated the *I. dammini* spirochete from the blood, skin lesion, and spinal fluid of patients with Lyme disease and demonstrated antibody to this organism in these patients. Steere declared, "*Ixodes dammini* spirochete is the causative agent of Lyme disease." The isolation was the first identification of an infectious organism causing symptoms and signs similar to rheumatoid arthritis.

I. dammini spirochete is thought to have traits of both Treponema and Borrelia genera. *I. dammini* spirochetes are morphologically like Treponema but, unlike Treponema, *I. dammini* spirochete can be cultured in vitro. (Recent taxonomy classification has designated this organism *Borrelia burgdorferi.*)

Neurologic and cardiac abnormalities of Lyme disease have many similarities to other spirochetal infections. Dermatologic abnormalities (ECM) and intermittent and chronic arthritis seem to be unique to Lyme disease.

Laboratory Findings

Specific laboratory testing for Lyme disease is limited. The erythrocyte sedimentation rate may be elevated during periods of active disease. Activation of the immune system has been indicated by changes in levels of immune globulins and presence of cryoglobulins containing specific IgM antibody. Some patients with Lyme disease have had transient elevated liver enzymes, mild anemia, and hematuria without evidence of chronic renal involvement.

Tests for uric acid, antinuclear antibodies, rheumatoid factor, and changes in ASO titers have been consistently unrewarding. An indirect fluorescent antibody test for the *I. dammini* spirochete is available at certain laboratories. Culturing for *I. dammini* spirochetes is a difficult procedure with very low yield.

Treatment

Patients who receive antibiotics early in the course of Lyme disease have fewer clinical difficulties. Antibiotics shorten the duration of ECM and can prevent or ameliorate subsequent joint, nerve, or heart complications. Early treatment is thought to blunt the immune response. Oral tetracycline or penicillin are recommended antibiotics for treatment of Lyme disease. Intravenous penicillin in high doses has been used to treat neurologic abnormalities associated with this illness. Approximately 14 percent of antibiotic-treated patients with severe Lyme disease develop a Jarisch-Herxheimerlike reaction (fever, chills) during the first 24 hours following the start of therapy.

Other medications have been tried for treatment of the complications of Lyme disease. Prednisone is useful in treating the neurologic and cardiac problems. Aspirin, other nonsteroidal anti-inflammatory drugs, and intra-articular medications have had inconsistent effects on acute and chronic joint involvement.

Conclusions and Questions

Lyme disease has now been well defined. Criteria for clinical diagnosis, isolation of the causative organism, identification of a vector, important laboratory findings, and recommended treatment have been elucidated. Investigators are continuing to ponder (1) whether the persistent presence of *I. dammini* spirochete in the body perpetuates Lyme disease or (2) whether the infectious agent triggers disease due to an autoimmune response.

Is Lyme disease only ixodic? Can other biting or stinging arthropods be vectors for Lyme disease? Our patient reported a history (confirmed by her parents) of being bitten by a "skinny, black, flying bug." The site of the bite was craterlike and immediately painful and pruritic—characteristics of the bite of an aggressive female deer or horse fly. Steere discounted recollections of three patients who blamed their ECM lesions on the bite of a deer fly. The organism responsible for tularemia is transmitted by both ticks and biting flies.

That leads to the suggestion that arthropods other than *I. dammini* (or *I. pacificus*) ticks may serve as vectors for Lyme disease. On the basis of the case reported, the assumption could be made that an infected tick passed the infectious agent to a white-tailed deer, inducing a spirochetemia in the deer. A blood-sucking fly bit the deer, became infected, and passed the *I. dammini* spirochete to our patient, resulting in her illness.

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Lyme Disease

My family and I were residents of Old Lyme, Connecticut from 1968 to 1976. In October 1974 I was told that my eight-year-old daughter, Anne, had juvenile rheumatoid arthritis (JRA). Anne came home from school complaining of a painful knee, which was swollen and warm to the touch. The following morning her knee was still swollen, so I called an orthopedic surgeon. After examining Anne that day, he admitted her to Lawrence and Memorial Hospital with a diagnosis of osteomyelitis. He drained and cultured the joint and placed her on intravenous antibiotics.

The second morning the other knee was inflamed and Anne was unable to move either joint. Cultures came back negative and there was no evidence of bacterial infection. My husband, a pathologist at the hospital, did serum studies that also failed to reveal a viral infection. With all test findings negative, intravenous antibiotics were stopped, and Anne was sent home in a wheelchair with instructions for aspirin therapy of ten aspirins a day. Her weight at the time was 40 lbs.

An eleven year old next door neighbor had spent the previous summer confined to a wheelchair with JRA; the child's father had arthritis. Another eleven-year-old living on our street had been diagnosed as having JRA, and a six-year-old girl who lived around the corner had JRA; the girl's mother had arthritis.

I grew up in New York City and had never seen or met anyone with the disease. I was amazed at personally knowing five people, four living on the same street, with the same disease.

Eight years ago Old Lyme was a town of about 4,000 people. Situated two hours northeast of New York City and two hours southwest of Boston, it was a beach resort town on Long Island Sound with two lakes, forests, no industry, one supermarket, a drugstore, a town library, a few specialty shops, and a marina on the Connecticut River. Old Lyme residents would stop me in the supermarket or library, the only two places for the local people to congregate, to ask about Anne. Many would mention children they knew with the same problem.

I called the only physicians practicing in town, two general practitioners. I told them I thought it strange to hear about so many cases of JRA in our little town. I asked how many cases of JRA they had. I had seen both men professionally at one time or another, and they were very gracious with their time. They told me most people in town did not come to them; their practices consisted of people from neighboring towns. They did see JRA but did not know how many cases they had. I called Anne's orthopedic surgeon and asked how many cases he had. He said he had many cases, but that I was overreacting and making a big deal over a disease that was not unusual. I contacted Anne's pediatrician. We had kept him informed of her progress. His response was the same: "this is a common problem, I see cases, I don't know how many." I called a pediatrician (who previously had covered for our pediatrician) in a neighboring town and I heard the same thing.

I cannot convey effectively the terrible frustration I felt. The physicians were receptive to my calls; certainly they would be, my husband was the only pathologist in the area, and they all knew of him. Everyone heard me,

but nobody listened.

I called the Connecticut State Health Department in Hartford. Since JRA was not a contagious disease, they said they could do nothing. I called the Communicable Disease Center (now known as the Center for Disease Control) in Atlanta and was told much the same thing. I became very emotional and used language that I would rather forget. I was put on hold and eventually spoke with a physician who tried to calm me down. I do not know whether he was an epidemiologist or a psychiatrist, but he did calm me down. He suggested I call Dr. Allen Steere at Yale.

To my astonishment, Dr. Steere was very receptive. He listened and asked that I contact the people I knew and ask them to call him. He arranged a meeting at the Old Lyme Town Hall to gather their medical histories. Eventually he gained a grant and started seeing these patients at Yale. This led to the discovery of Lyme disease or Lyme arthritis.

I recently was interviewed by a visiting physician from Canada who is writing an article for the Encyclopedia Britannica. He wanted to know why I persisted. One reason was my disappointment in the medical surveillance establishment for not doing what they should have with the unusual situation. I also was concerned about my daughter's future and hoping for a better prognosis. I hope the chain of events that led to the discovery of this new disease will help physicians listen to laymen rather than to prejudge a clinical situation.

Anne is perfectly healthy nine years later. She has had no recurrence and no chronic effect from her disease, most likely because she was treated early with intravenous antibiotics for the original diagnosis of osteomyelitis. Our orthopedic surgeon treated her right for the wrong reason.

JUDITH MENSCH
Gaithersburg, MD

Consultation

The Faculty's radio program on WBJC-FM (91.5 mHz on your dial)
is on the air between 10 and 11 a.m. on alternate Wednesdays

July 24	**Sports Medicine**	William Howard MD Neil MacDonald
August 7	**Treatment of Cancer Today**	George Elias MD
August 21	**Early Childhood Development**	Barbara Howard MD
September 4	**Immunizations**	Robert Ancona MD
September 18	**How to be a Wise Consumer of Health Care**	Donald T. Lewers MD
October 2	**Osteoporosis**	Robert D. Katz MD
October 16	**Pain, How to Stand It**	Nelson Hendler MD
October 30	**AIDS**	Frank Polk MD

What A Physician Should Know About Ovarian Cancer

UMBERTO VILLASANTA MD

The diagnosis of ovarian cancer is commonly unsuspected before surgery and not made until the initial surgical procedure. The general surgeons or gynecologists who find the disease often are not prepared for this eventuality. When the patient is referred to the gynecologic oncologist, specific information often is not available; equally often the optimal operation had not been done. Physicians can do much to improve the prognosis for these patients.

Dr. VillaSanta is at Division of Gynecologic Oncology, Department of Obstetric and Gynecology, University of Maryland School of Medicine, Baltimore, Maryland.

Cancer of the ovary is becoming more common every year. It is not the most frequent gynecologic malignancy yet it has achieved the undesirable distinction of being the most lethal neoplasm encountered in gynecology[1] (Table 1). The low survival rate is probably because over half the ovarian cancers are diagnosed late, in Stages III and IV. (Staging usually is done at exploratory laparotomy and follows the recommendation of the International Federation of Obstetrics and Gynecology (FIGO) (Table 2).) According to *Annual Report*, Volume 17, of FIGO[2] 42.6 percent of reported ovarian cancers were Stage III and 18.3 percent were Stage IV for a total of over 60 percent in Stages III and IV.

Signs and symptoms of ovarian cancer are not diagnostic and are common in a large variety of diseases. Symptoms of patients with ovarian cancer are: nausea, vomiting, dyspepsia, dyspnea, abdominal distension, malaise, constipation, anorexia, abdominal pains, menstrual irregularity or postmenopausal bleeding, and loss of weight. Findings may include: pleural effusion, ascites, abdominal mass, liver enlargement, ureteral obstruction with hydronephrosis or nonfunctioning kidney, hematuria, intestinal obstruction (partial or complete), and melena.

Most commonly, a patient is seen by a family practitioner or specialist in internal medicine for symptoms not thought to be related to gynecologic pathology. The patient is examined thoroughly and has a large number of blood, x-ray, and scan (ultrasound and CT) examinations. However, the bottom line of the chart too often reads "pelvic and rectal examination deferred."

When a gynecologist is requested to see the patient the pelvic examination might reveal a pelvic mass. In the differential diagnosis the following must be considered: functional, inflammatory, and neoplastic masses of the adnexa and myomata; distended bladder; pelvic kidney; bladder tumors; diverticulitis; intestinal abscesses or tumors; and retroperitoneal sarcoma.

The diagnosis can be proved by laparotomy only; thus, the patient eventually is brought to the operating room for exploratory laparotomy. The operator often is not prepared to perform the proper therapeutic operation. Appropriate amounts of blood may not be available. The patient is not prepared psychologically, mechanically, or chemically; the possibility of a colostomy was not discussed with the patient. A Pfannenstiel incision, inadequate for ovarian cancer surgery, is performed.

When the patient ultimately is referred to an oncologist or oncology center her future treatment is hampered by lack of adequate information about the true extension of the tumor. There is no result of peritoneal washing; there was no intraoperative evaluation of dia-

Table 1. American Cancer Society 1985

	New Cancers	Deaths
Cervix	15,000	6,800
Endometrium	37,000	2,900
Ovary	18,500	11,600

Table 2. Stages of Ovarian Cancer

Stage I. Growth limited to the ovaries
- Stage Ia. Growth limited to one ovary; no ascites
  - (1) No tumor on the external surface; capsule intact
  - (2) Tumor present on the external surface and/or capsule ruptured
- Stage Ib. Growth limited to both ovaries; no ascites
  - (1) No tumor on the external surface; capsule intact
  - (2) Tumor present on the external surface and/or capsule(s) ruptured
- Stage Ic. Tumor either stage Ia or Ib but with ascites* or positive peritoneal washings

Stage II. Growth involving one or both ovaries with pelvic extension
- Stage IIa. Extension and/or metastases to the uterus and/or tubes
- Stage IIb. Extension to other pelvic tissues
- Stage IIc. Tumor either stage IIa or IIb, but with ascites* or positive peritoneal washings

Stage III. Growth involving one or both ovaries with intraperitoneal metastases outside the pelvis and/or positive retroperitoneal nodes or tumor limited to true pelvis with histologically proven malignant extention to small bowel or omentum

Stage IV. Growth involving one or both ovaries with distant metastases. If pleural effusion is present there must be positive cytology to allot a case to stage IV

Special Category. Unexplored cases which are thought to be ovarian carcinoma

* Peritoneal effusion which in the opinion of the surgeon is pathologic and/or clearly exceeds normal amounts.

phragmatic, hepatic, para-aortic or omental metastases; an attempt to reduce the bulk of the tumor was not made.

Although it is more commonly seen in older women, cancer of the ovary can be found at any age (Table 3).[3] In infant, prepubertal, and teenage girls germ cell tumors such as dysgerminomas, embryonal carcinomas, endodermal sinus tumors, and choriocarcinomas are most frequently encountered. These tumors are highly malignant and radioresistant (except for dysgerminomas). If localized, they can be treated with simple excision that prevents castration followed by triple agent chemotherapy (vincristin, actinomycin D, and cyclophosphamide). After six months of chemotherapy a "second look" operation is recommended.

In adult and postmenopausal women tumors can originate from ovarian stroma and include theca-granulosa cell tumors, androblastoma (Sertoli-Leydig Cell Tumors), and sarcomas. These are rare and frequently produce hormones (estrogen, testosterone, serotonin).

The most common tumors in adult females are epithelial tumors, representing over 90 percent of all malignant neoplasms and originating from the celomic epithelium on the surface of the ovary. In order of decreasing frequency they are: serous cystadenocarcinomas, mucinous cystadenocarcinomas, endometroid carcinomas, clear cell carcinomas, and undifferential carcinomas. The five-year survival for all patients with ovarian malignant tumors, as reported in the FIGO Annual Report of Gynecologic Cancer, Volume 16, is as follows:

	Percent
Stage I	64.9–65.7
Stage II	40.9–42.9
Stage III	2.2–10.1
Stage IV	0 – 1.9

Table 3. Age and Incidence of Ovarian Cancer Carcinoma

Age	Incidence per 100,000
15–20	3.6
20–24	3.8
25–29	4.9
30–34	5.9
35–39	11.6
40–44	16.9
45–49	32.2
50–54	34.7
55–59	48.4
60–64	47.2
Over 65	32.0

Incidence

Ovarian cancer incidence rises sharply after age 40 up to age 70 when it declines.[4] Never married females have a considerably higher morbidity rate than ever married.[5] The rate and magnitude of increase are almost identical in Caucasian and non-Caucasian females until about the age of menopause when the non-Caucasian rate levels off and declines around ages 60 and 65. The rate for Caucasian females continues to rise sharply for another decade.

As a result of research on animals[6] irradiation has been considered cancerogenic. Epidemiological studies found race, marital status, and previous irradiation have no role in producing ovarian malignancies[7,8] while mumps-parotitis appears to significantly prevent occurrence of ovarian cancer.[9] Nulliparous women, regardless of marital status, have 2.31 times more risk of developing ovarian cancer than parous women.[10,11] Hormonal influence in producing cancer has been implicated,[12] but subsequent epidemiologic studies found no relation between administration of estrogen and progesterone (as in oral contraception) and ovarian cancer.[13–15] Increased incidence of ovarian cancer has been found in women with family history of both benign and malignant ovarian lesions.[16,17]

Preoperative Procedures

In addition to the general physical examination and rectopelvic evaluation, the proper preoperative work-up of a patient with a possible ovarian tumor must include: an EKG, chest x-ray, liver scan, intravenous pyelogram, barium enema, upper gastrointestinal follow-through, CBC with differential and platelet counts, urinalysis, SMA 6, serum creatinine, and bilirubin.

Preoperative preparation of the patient must provide: mechanical and chemical preparation of the bowel; correction of electrolytes, fluid, and hemoglobin imbalance; prophylactic heparin; adequate units of blood cross matched; and a proper discussion with the patient of possible organ removal and fecal or urinary diversion.

Initial diagnostic and therapeutic surgery usually is inadequate, and a repeat laparotomy is necessary for proper assessment and staging. Laparoscopic examination was found inadequate for this purpose. Prognosis is directly proportional to the volume of tumor left behind. Cytoreductive surgery is mandatory in order to proceed to the second stage of treatment; chemotherapy.

Initial surgery must be done through a vertical incision extended above the umbilicus. As soon as the peritoneal cavity is entered, normal saline is squirted in the right gutter, left gutter, and pelvis, re-aspirated,

and sent for cytologic examination. A positive abdominal washing always is associated with poor survival. Liver and diaphragm must be visualized and possibly biopsied. Para-aortic lymph nodes always must be sampled. A partial omentectomy is mandatory; omental metastases are frequently early in the natural history of this disease. All suspicious areas should be biopsied.

Unilateral oophorectomy is accepted in young women with limited disease and no gross evidence of metastases; it is always possible to go back and remove the remainder if evidence of metastatic disease is found. In older patients and with evidence of neoplastic spread, total removal of tumor must be attempted (total hysterectomy and bilateral salpingo-oophorectomy) plus removal of all gross cancer; this may mean cutting through the tumor. The less tissue left behind, the more effective chemotherapy will be.

Chemotherapy should be started as soon as the healing process is completed (usually two to three weeks after initial surgery). A variety of drugs are beneficial. Single drug chemotherapy achieves less optimal results than multiple drug chemotherapy.[18] At University of Maryland Hospital a combination of continuous intravenous infusion of fluxuridine for five days and intermittent intravenous "push" cyclophosphamide for five days has produced the best results.[19] Intravenous cisplatinum has been used as an alternate drug in cases of hematuria, allergic reaction, or failure. Dose reduction is advisable for impaired bone marrow, liver, or kidney function.

At least twelve courses of chemotherapy at three-week intervals should be given; if no tumor is found on clinical or x-ray examination, a "second-look" operation should be performed. This must include a complete surgical evaluation of the patient: vertical incision; peritoneal washing; visualization and biopsies of liver, diaphragm, omentum, para-aortic lymph nodes, adhesions, stumps of infundibulopelvic ligaments, and pelvic peritoneum.

If no evidence of tumor is found, no further therapy is advised. If tumor is present, a second-line drug chemotherapy is tried. Radioactive isotopes or radiation therapy are not used as frequently as in the past because these treatments have frequent and serious complications.

Response to Treatment

In evaluating response to treatment, various parameters can be used: objective changes in tumor size, intracavitary fluids or products of tumors, duration of response, median survival time, subjective response, or reduction of tumor for three months. This is useful for research but does not add to length and quality of life of the sick patient. As in other cancers, the only accepted evidence of response should be five-year tumor-free survival from onset of treatment.

The surgical and chemotherapeutic regime previously outlined achieved the following results at five years: Stage III, 35 percent survival (Table 4); Stage IV, 12 percent survival (Table 5).

The number of therapy courses received by patients and the largest diameter of residual disease after the first surgical exploration are important. The importance of cytoreduction surgery must be emphasized. If these two factors are combined, a small tumor treated with at least nine courses of chemotherapy offers the best prognosis (Table 6).

"Second-look" findings are important for prognosis. Unfortunately, the procedure can be misunderstood and abused. If the patient has any clinical, x-ray, or scan evidence of residual disease, exploratory laparotomy

Table 4. Ovarian Cancer Stage III 5-Year Survival

	Patients Treated	Percent
Alive	9	35
Died of intercurrent disease	3	11
Lost to follow-up	2	8
Dead of disease	12	46
	26	

Table 5. Ovarian Cancer Stage IV 5-Year Survival

	Patients Treated	Percent
Alive	3	12
Died of intercurrent disease	2	8
Lost to follow-up	–	
Dead of disease	20	80
	25	

Table 6. Five-year Survival—Stages III and IV Less than 2 cm Residual Disease and 9 or More Courses of Chemotherapy

	Patients Treated	Percent
Alive	7	50.0
Died of intercurrent disease	2	14.3
Lost to follow-up	1	7.1
Dead of disease	4	28.6
	14	

with intent to remove residual or recurrent tumor is indicated. The second-look procedure must be used only in patients who have no clinical or radiological evidence of residual or recurrent cancer.

In 51 patients who had the second-look operation at University of Maryland Hospital, 33 had negative and 18 positive findings. Of the 18 patients with positive findings, three (with only microscopic residual) are alive with no evidence of disease five years later. Of the 33 patients with negative findings, 23 are alive and well after five years (Table 7).

A negative "second look" is not a 100 percent guarantee of survival even if the prognosis for the patient is excellent. With additional chemotherapy a few patients with residual tumors can be alive and free of cancer five years later.

Table 7. Cancer of Ovary
5-Year Survival After "Second-Look" Operation

Negative 33	Alive	23
	Dead of intercurrent disease	4
	Lost to follow-up	3
	Dead of disease	3
Positive 18	Alive	3
	Dead of intercurrent disease	2
	Dead of disease	13

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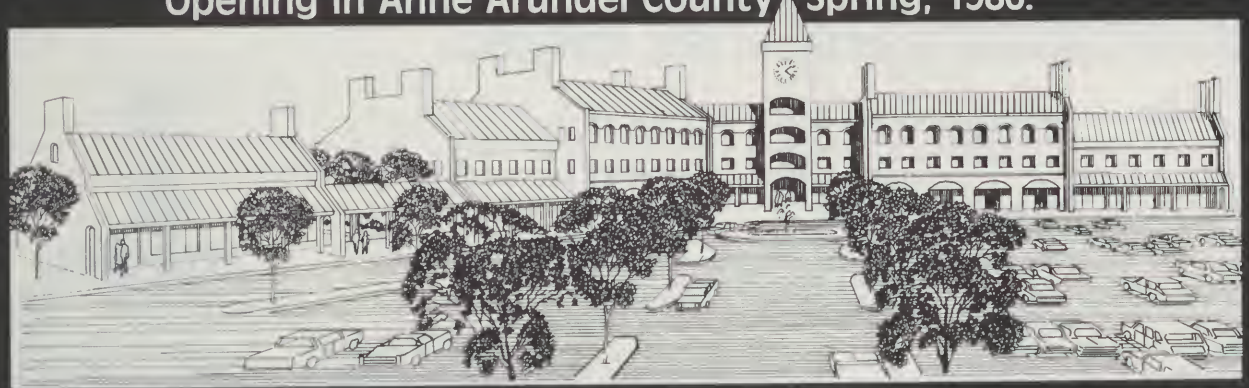
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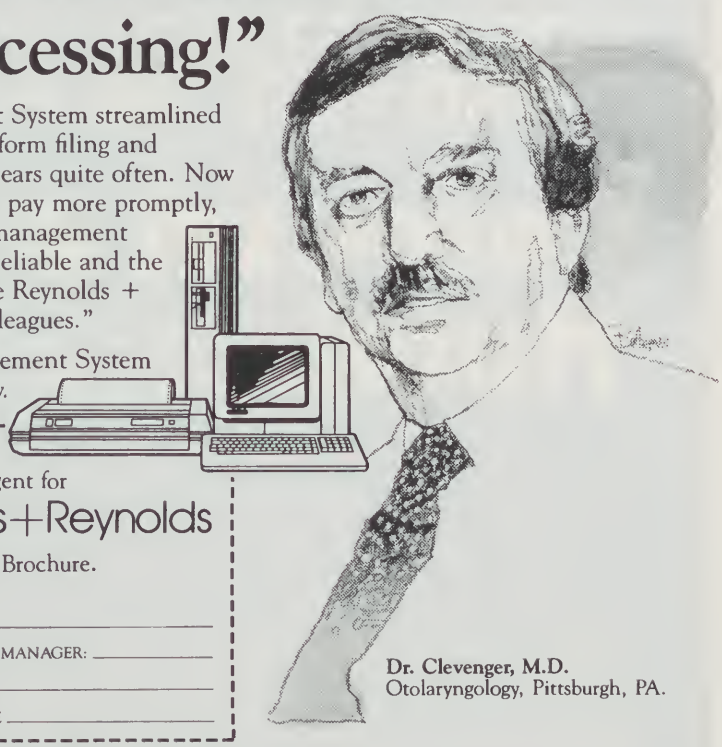
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Members in the News

Elihu E. Allinson MD, Baltimore, retired as chief of psychiatry at North Charles General Hospital and was named emeritus chief, department of psychiatry, permanent member of the Honorary Medical Staff of the hospital.

• • •

Franklin L. Angell MD, Severna Park, chairman of Radiology at Mercy Hospital, has been appointed to a prestigious six-year term as a trustee on the American Board of Radiology. As trustee, he will work with the Board on issues such as improving radiology graduate education, evaluating training standards, and determining competence of radiology specialists.

Dr. Angell is a graduate of the Medical College of Virginia in Richmond and has served as chairman of Radiology at Mercy Hospital since 1970. He is a professor of Radiology at the University of Maryland School of Medicine.

• • •

August D. King, Jr., MD, Towson, has been elected president of the medical staff at Mercy Hospital. Dr. King is a graduate of the University of Maryland School of Medicine where he serves as instructor of surgery. He is also surgeon for the Baltimore City Police department.



Jose Martinez MD, section head of nuclear medicine and diagnostic ultrasound at Fallston General Hospital, has been elected president-elect of the American College of Nuclear Physicians, 1,200 member national organization.

Dr. Martinez received his medical degree from Alexandria University in Alexandria, Egypt. He served internships at the Hospital of the Egyptian Ministry of Public Health and Alexandria University Hospital, and Church Home and Hospital in Baltimore. He completed his residency in internal medicine at Church Home and Hospital. In addition, Dr. Martinez served a fellowship in internal medicine and nuclear medicine at Johns Hopkins University School of Medicine.

• • •

David P. Zajano MD, Phoenix, was installed as President of the Maryland Academy of Family Physicians during the organization's Annual Meeting and Scientific Session held in Ocean City. The installation coincided with the signing of a proclamation by governor Harry Hughes declaring the week of May 5 to 12 as Family Practice Week in Maryland.

The Academy consists of almost 60,000 members and is the largest medical specialty organization in the country.

Dr. Zajano received his medical degree from Hahnemann Medical College in 1973 and served as a rotating intern at Franklin Square Hospital in Baltimore from 1974–75. He began his residency there in 1974 and served as chief resident in the Department of Family Practice at Franklin Square.

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Discipline Commission Action

In the Matter of
Matthew S. Atkinson III, MD
Before the
Commission on Medical
Discipline of Maryland

Order for Emergency Suspension of License
Background

On or about March 25, 1985, the Commission on Medical Discipline of Maryland (the "Commission") received a Psychiatric Evaluation from Jonas R. Rappeport MD concerning the psychiatric condition of Matthew S. Atkinson III, MD (the "Respondent") (see Exhibit 1 attached hereto). This evaluation was submitted to the Commission as a result of a psychiatric examination of the Respondent performed by Dr. Rappeport pursuant to a letter of the Commission to the Respondent directing Respondent to submit to a "complete psychiatric examination" (see exhibits 2 and 3 attached hereto). The above described psychiatric examination was performed on March 21, 1985, and the evaluation submitted consists of a mental status examination, a diagnostic impression of Respondent's mental disorder, and a summary and recommendations including a recommendation that Respondent's "chronic manic depressive illness is not under sufficient control to make it a reasonable risk to allow him to practice medicine at this time."

Findings of Fact

Specifically based on information provided the Commission as set forth above as well as on the information described below, the Commission makes the following findings that:

1. Respondent is a physician licensed to practice in that State of Maryland;

2. Respondent came to the attention of the Commission on December 10, 1982 as a result of a complaint filed by Jerold Kempler PD, a licensed pharmacist, in which it was alleged that Respondent improperly prescribed certain controlled dangerous substances (see exhibit 4 attached hereto).

3. Pursuant to the provisions of Health Occupations Article §14-501 the Commission referred the complaint to the Medical and Chirugical Faculty of Maryland for investigation; as a result of that investigation it was determined that Respondent was an in-patient at Springfield State Hospital and that he had prescribed drugs for a friend while he was on weekend leave (see exhibit 5 attached hereto).

4. On March 7, 1985 in order to assess Respondent's current medical condition the Commission ordered Respondent to submit to a complete mental competence examination before Jonas R. Rappeport MD.

5. The psychiatric evaluation submitted to the Commission by Dr. Rappeport gives a diagnostic impression for Respondent as "bipolar—manic—chronic in partial remission." The evaluation further states that Respondent "is clearly barely under control, loud, garrulous, somewhat argumentative, particularly hostile and negative towards his wife while at the same time revealing his entire history and in essence making it clear that he is a very sick person and has been unable to manage things very well in recent years." The evaluation further indicates that Respondent is no longer an in-patient at a psychiatric facility.

6. In the psychiatric evaluation Dr. Rappeport informed the Commission that in his opinion "Dr. Atkinson's chronic manic depressive illness is not under sufficient control to make it a reasonable risk to allow him to practice medicine at this time."

7. Based on the information received by the Commission the Commission has reason to believe that Respondent is mentally ill and that as a result of this illness he is unable to practice medicine competently because he is mentally incompetent.

8. For the reasons set forth in the foregoing paragraphs, the Commission concludes that emergency action is required in this case pursuant to §10-405 of the State Government Article of the Annotated Code of Maryland (The Administrative Procedure Act) because in light of Respondent's mental incompetence his continued possession of a license to practice medicine poses an imminent and grave danger to the public health, welfare, and safety.

Order

It is this 8th day of April 1985 by the Commission on Medical Discipline of Maryland:

ORDERED that pursuant to the authority vested in the Commission by the State Government Article, §10-405 of the Annotated Code of Maryland, Respondent's license to practice medicine is hereby SUMMARILY SUSPENDED; and be it further

ORDERED that on presentation of this Order, Respondent shall immediately deliver to the Commission;

1. His complete license to practice medicine in the State of Maryland; and be it further

2. All permits to prescribe controlled dangerous substances which are issued to Respondent; and be it further

ORDERED that a hearing shall be held before the Commission within thirty (30) days of the date upon which the Board receives a request from the Respondent for a hearing to consider this emergency suspension.

***KARL F. MECH MD,* Executive Secretary**
Commission on Medical Discipline of Maryland

On instruction of the Council of the Medical and Chirurgical Faculty of the State of Maryland, "Findings of Fact, Conclusions of Law, and Order" will be published in the Maryland Medical Journal.

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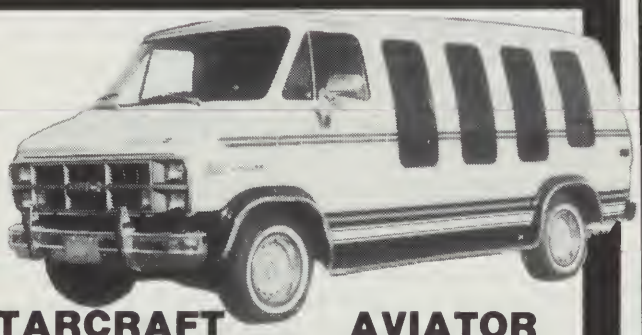
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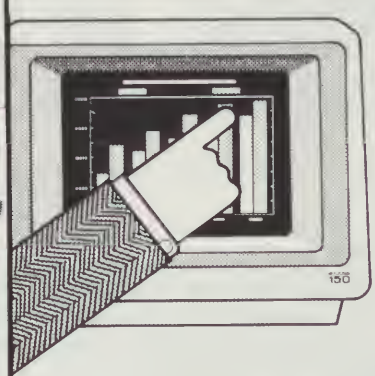
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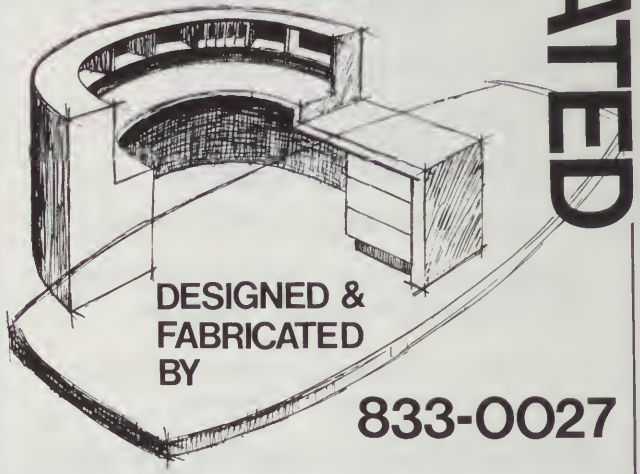
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Sep 6–7 Fourteenth Annual Diagnostic Ultrasound in Obstetrics and Gynecology at the Baltimore Plaza Hotel. Fee: $240 physicians, $165 sonographers/technicians; 12 AMA Cat I credits.

Sep 20–21 Rheumatology Update, 1985, sponsored by The Johns Hopkins University School of Medicine, The Maryland Society for Rheumatic Diseases, Maryland Lupus Foundation, and The Arthritis Foundation, Maryland Chapter. Fee: $100 physicians, $50 arthritis health professions, $50 nurses; 1 AMA Cat I credit.

Oct 3–5 Eleventh Annual Topics in Gastroenterology and Liver Disease. Fee: $300 physicians, $150 Residents and Fellows; application has been made for 20 AMA Cat I credits.

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Aug 4–9 An Intensive Review of Internal Medicine, Jefferson Medical College in cooperation with the University of Delaware, 45 Cat I AMA credits. Info: S. Brocka, University of Delaware, 2800 Pennsylvania Ave., Wilmington, DE 19806 (302-573-4400).

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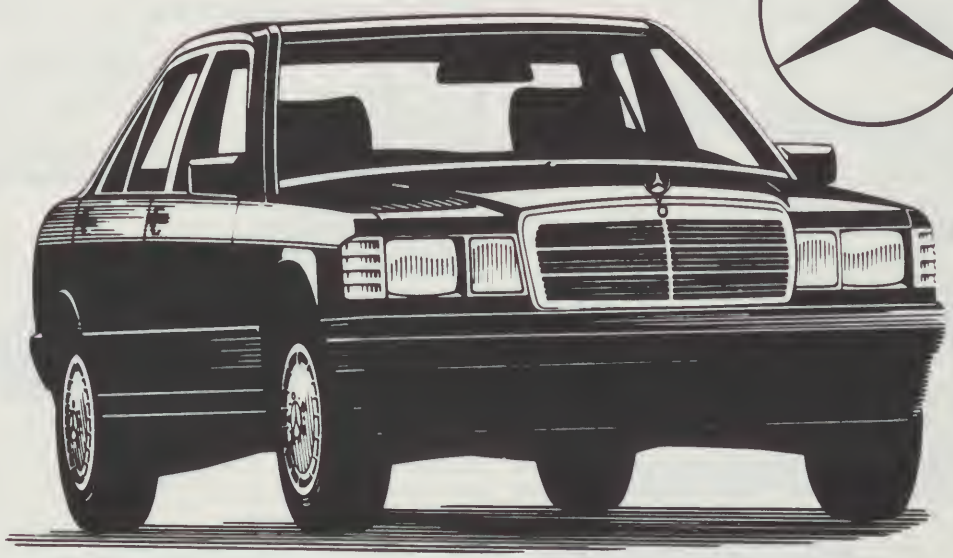
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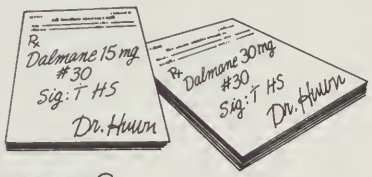
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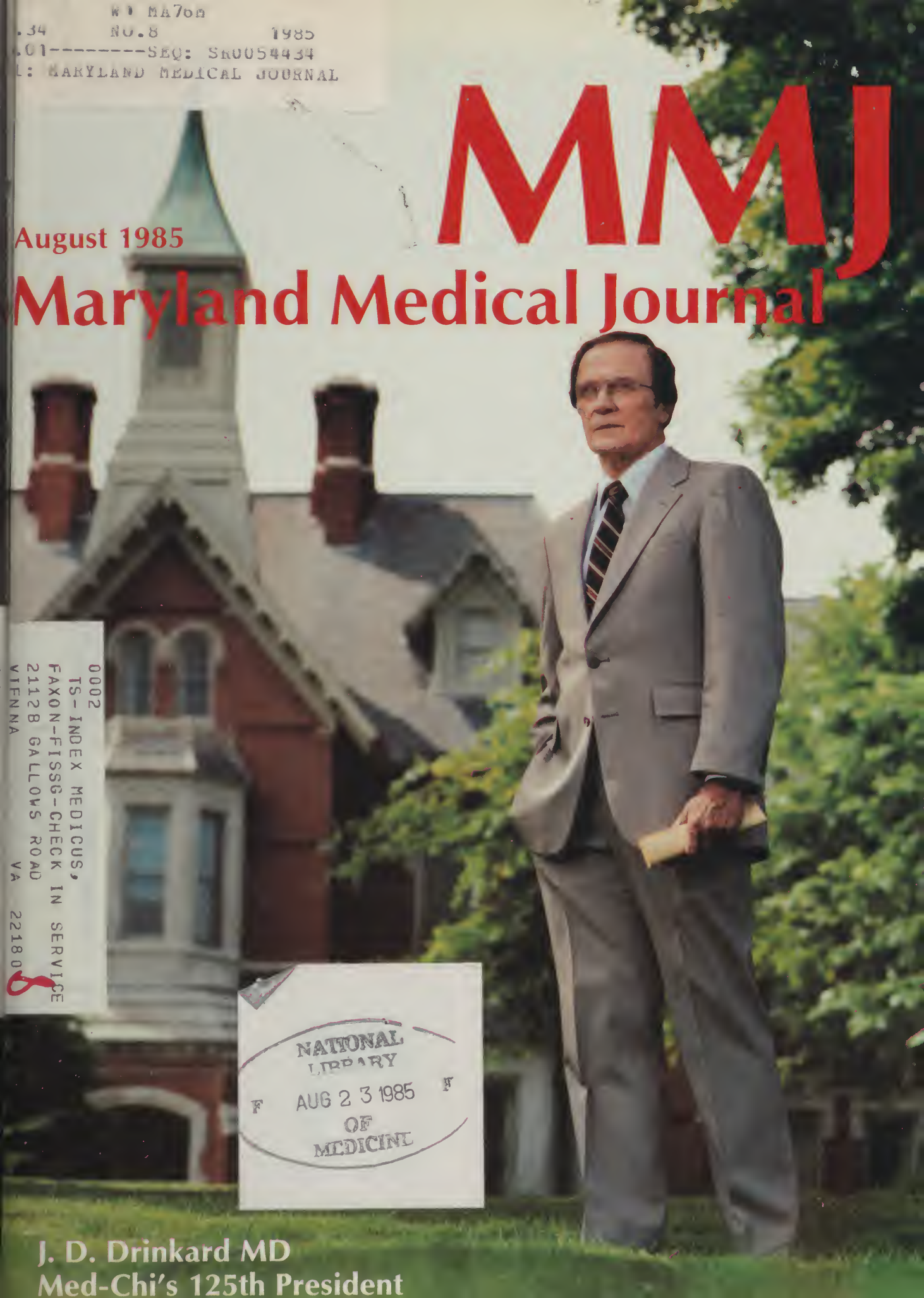
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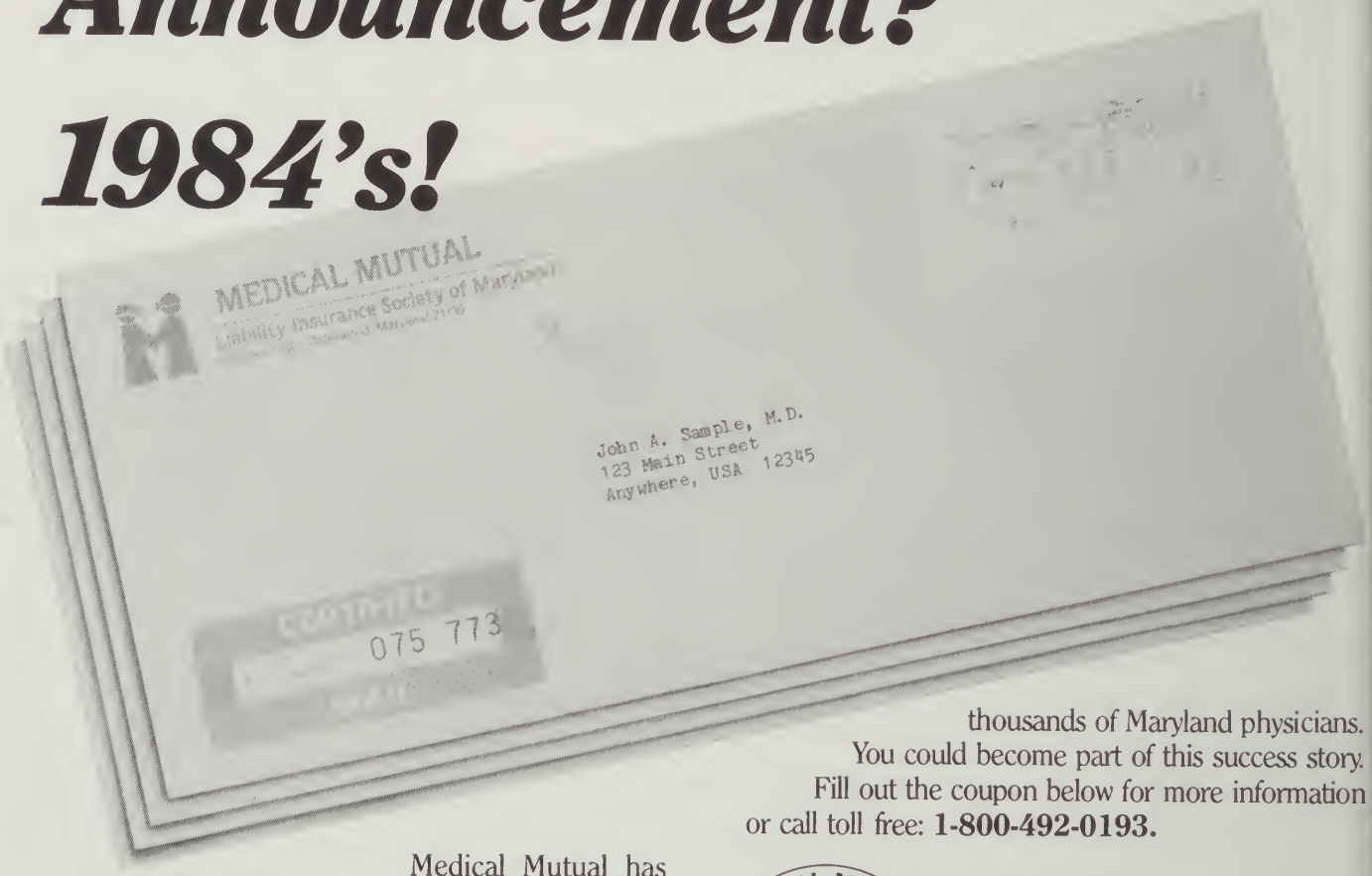
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MISCELLANY

Executive Director's Newsletter 731
Medical Miscellany 735, 743
Consultation 736
Medicolegal Hotline 775
Hotline Numbers 798, 822
Doctors Take Note 817
Physician Placement Service 818
Change of Address Form 818
Information for Authors 825
Classified Ads 827
Advertisers' Index 829

ARTICLES

Med-Chi's 125th President: J.D. Drinkard MD 757

Remarks at the Presidential Banquet—George S. Malouf MD 761

ANNUAL REPORTS

Index 762

DEPARTMENTS

Semiannual Meeting Announcements 741

Your Medical Faculty at Work 743

Disease Control Newsletter 745

On the cover: J. D. Drinkard MD, a Towson psychiatrist, has had a long affiliation with the Sheppard and Enoch Pratt Hospital. Article begins on page 757. All photos in this issue are by TADDER/Baltimore.

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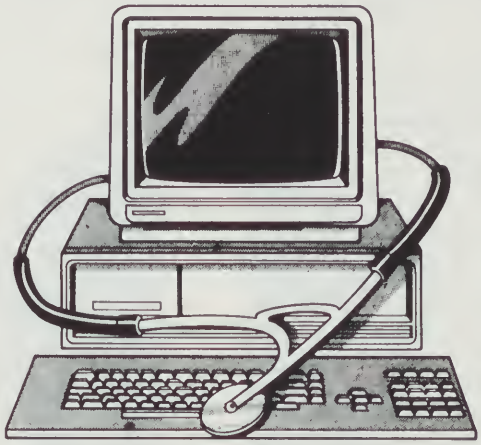
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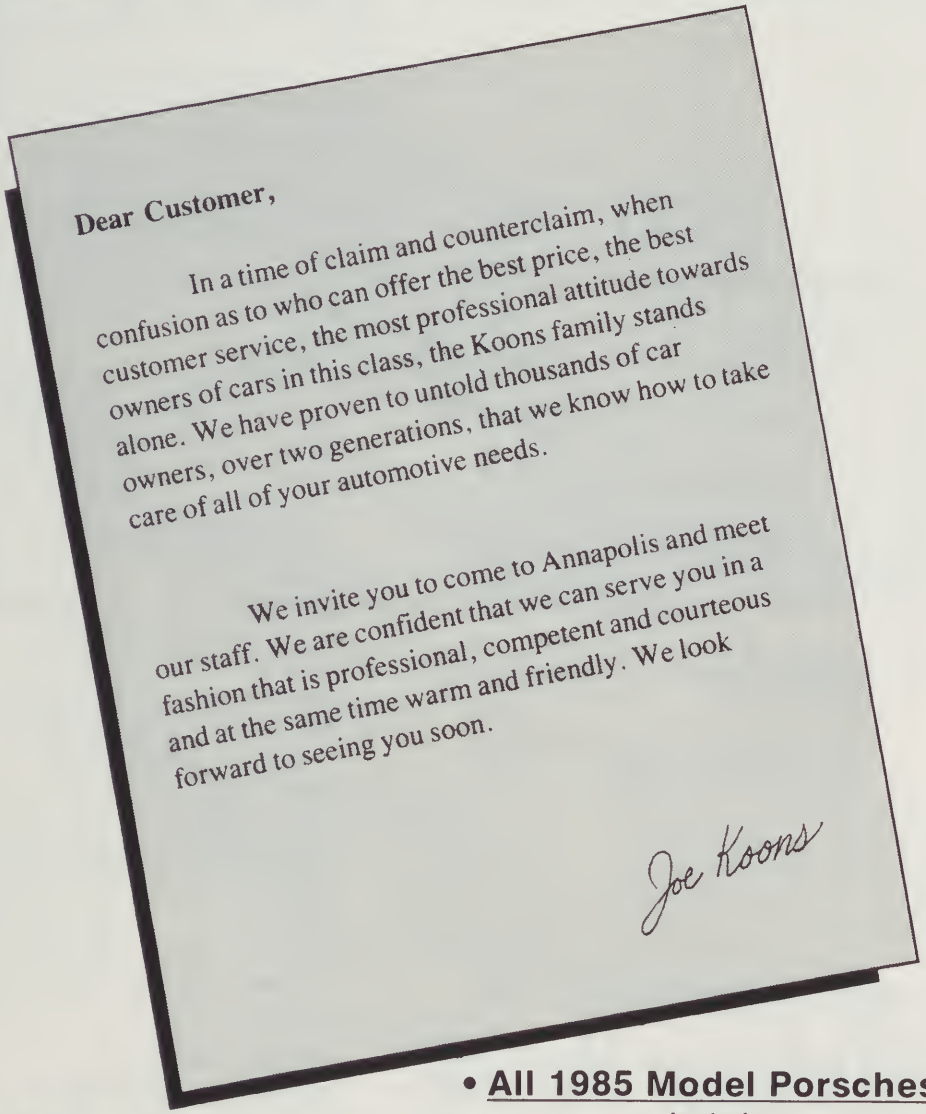
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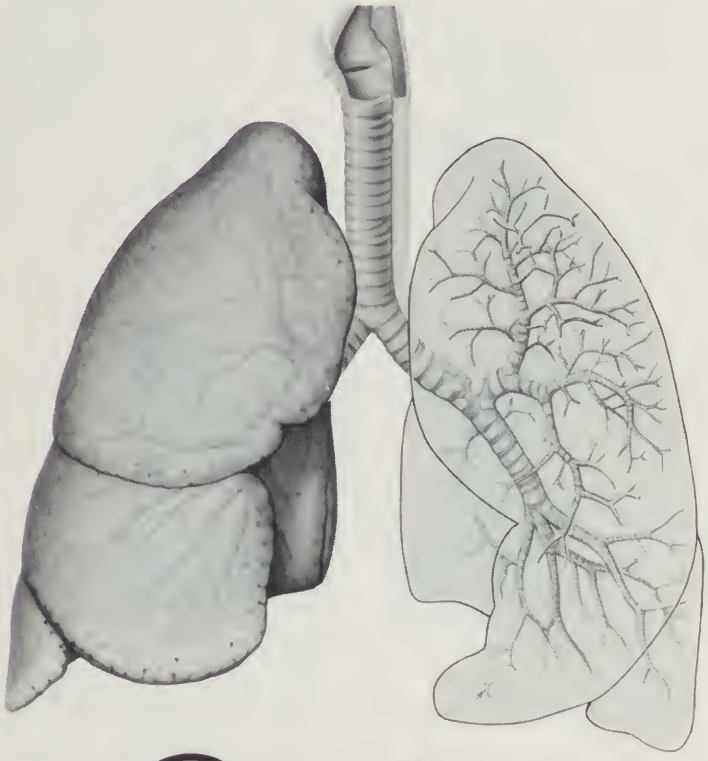
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Brief Summary. Consult the package literature for prescribing information.

Indications and Usage: Ceclor* (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae* (*Diplococcus pneumoniae*), *Haemophilus influenzae*, and *S. pyogenes* (group A beta-hemolytic streptococci).

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor.

Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Precautions: *General Precautions* — If an allergic reaction to Ceclor* (cefaclor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest* tablets but not with Tes-Tape* (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy — Pregnancy Category B — Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor* (cefaclor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers — Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Ceclor is administered to a nursing woman.

Usage in Children — Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below.

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbiliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic — Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic — Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal — Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[0617B2R]

Note: Ceclor* (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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Executive Director's Newsletter

AUGUST 1985

PROFESSIONAL LIABILITY ISSUES

The Executive Committee called a special meeting to which it invited the President or an authorized representative of each component and statewide specialty society. All Councilors were also invited. Attendants heard:

> The Faculty has caused introduction of bills into the State General Assembly every year since 1975 to alleviate problems related to professional liability issues. None have been successful.
>
> Plaintiff's attorneys are alleging there is no crisis in affordability and the insurance reserving policies are causing the problem.
>
> Official physician representation has been obtained on the current Governor's Task Force formed to attempt resolution of this problem.
>
> A comparison of recent tort reforms enacted in Illinois, New York, and Florida reveals that many of these reforms have been in place in Maryland for some years.
>
> The climate in Annapolis seems favorable for some type of relief. However, other groups also are pressing for assistance in the area of liability insurance coverage. It is impossible to predict with accuracy what will occur.
>
> Members were urged to collect as much statistical data supporting the need for legislative action as possible. For instance, it is estimated that for each baby delivered, medical malpractice insurance adds $250-$300 to the costs for that delivery.
>
> Ongoing discussions are being held with legislative leaders in an attempt to find some resolutions to the difficulty.

At this session, the group unanimously directed the Executive Committee to ensure within 30 days, a plan be communicated to all component societies and statewide specialty societies outlining a coordinated campaign to seek legislative relief from the present professional liability problems.

BREAST CANCER PAMPHLET

<u>What You Are About to Read on Breast Cancer Could Save a Life...Yours</u> is available without charge from the Faculty office.

CONGRATULATIONS

Elza Davis recently received the Certified Association Executive certificate. This indicates competence in the field of association management and requires ongoing continuing education for use of the initials CAE following her name.

HENRY N. WAGNER ELECTED

Henry N. Wagner, Jr., MD, Baltimore, was elected by the AMA House of Delegates to the AMA's Council on Scientific Affairs. Dr. Wagner won the election by a substantial margin on the second ballot.

AMA TELECONFERENCE

A cassette tape of the AMA Teleconference on professional liability is now available from the Faculty office. To BORROW the tape, call the Communications Department at 539-0872 or toll-free in Maryland 1-800-492-1056.

MARKETING TECHNIQUES SEMINAR

The Faculty is planning two one-day seminars on "Marketing Techniques for Successful Practice" to be held Tuesday and Wednesday, November 5-6, 1985. One seminar will be held in the Baltimore City area and the other is planned tentatively for the Prince George's/Montgomery County area. Watch your mail for these upcoming seminars.

LICENSURE OF MAJOR MEDICAL EQUIPMENT

As you may be aware, the new program for licensure of major medical equipment is under way. The Faculty continues working with the Health Department to develop a final set of regulations. Toward that end, we need to know whether anyone has had problems obtaining a license. Please contact either myself or Judith Wood at the Faculty office with this information.

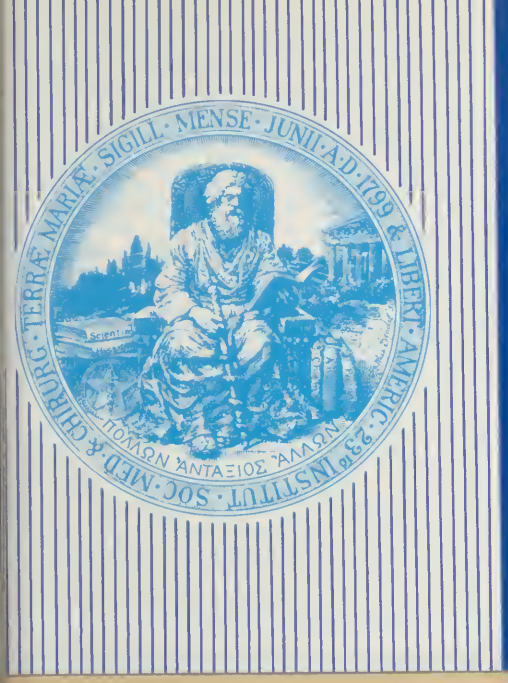
PRO REGULATIONS

The Faculty's Committee on Utilization and Quality Control Peer Review is still attempting to obtain information from physicians concerning patient complications that arise from the implementation of the PRO regulations. Such information should be accompanied by documentation, rather than anecdotal. If you feel the care of any of your patients has been compromised because of these regulations, write to the committee in care of the Faculty office.



Executive Director

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*JAMA, Volume 248, No. 3, pages 336-339
Yearbook of Medicine, 1983, pages 66-67

Medical Miscellany

AMA Survey and Opinion Briefs

Computer Use Among Physicians

Until recently, the use of computers in medicine has been largely confined to claims processing, billing, and record filling. However, computer technology, which is constantly improving, now includes software packages that aid in diagnosis and contain continuing medical education courses, as well as improving office efficiency.

For this reason, many federation organizations have become involved with various computer networks, including the AMA-GTE Telenet system. But how many physicians have access to a computer? And where is that access located? More importantly, how many physicians plan to obtain a computer in the near future and how often do they use computerized information services? The AMA's 1984 physician survey provides preliminary answers to these questions.

Extent and Location of Current Computer Access

Do you currently own or have access to a computer terminal and telephone-connection device (modem) in your home, in your office or in a local hospital?

	Home Percent	Office Percent	Local Hospital Percent
Yes	11	21	41
No	89	79	56

The data indicate that the home market is relatively undeveloped. Approximately two in ten physicians report access in the office and twice that number indicate the presence of a computer facility in a local hospital. In combination, 52 percent of physicians report computer access in at least one of the three locations listed.

Plan to Acquire Computer Access: The remaining 48 percent of physicians who report no access were asked:

Do you plan to acquire access to a computer terminal and modem within the next year?

	Percent
Yes	**22**
Unsure	**11**
No	**67**

More than two out of three physicians without any current computer access have no plans to acquire access in the near future. However, the 22 percent responding "Yes" suggests a growing future market although the data do not indicate whether these computers are for personal or professional use.

When this question is examined on the basis of age, younger physicians are substantially more likely than older physicians to indicate that they will acquire a computer in the near future.

	Under 45 Percent	45+ Percent
Yes	**29**	**18**
Unsure	**10**	**10**
No	**61**	**72**

As indicated, plans for access also vary by region.

East North Central	23	Pacific	16
West North Central	15	Mountain	31
East South Central	29	Middle Atlantic	25
West South Central	30	South Atlantic	27
New England	14		

Physicians from the Mountain and West South Central regions are more than twice as likely as New England residents to report plans to acquire computer access.

Current Use of Computerized Information Services

How often do you personally use computerized information services—that is, access information by using a computer terminal and a modem device?

	Percent
Never/hardly ever	63
Occasionally	18
Often/very often	16

By a large majority, physicians report never or hardly ever using computerized information services. Only a small portion, 16 percent, report frequent use. Again, when results are examined by age, the percentage of younger physicians reporting frequent use is substantially higher than that of their older colleagues.

Summary

The 1984 survey data indicate that approximately half of physicians have access to computers in either the home, office, or hospital setting, and that a quarter of the remainder plan to acquire computer services in the future. Of those that do use computers, the majority access them through their local hospital. However, young physicians and those in the Western and South Central states are more likely than other physicians to acquire access and use computers.

While over half of physicians have access to a computer, only 16 percent report frequent use of computerized information services. This difference suggests that many physicians are, as yet, unaware of the infor-

mation capabilities inherent in new computer systems. In a marketing sense, the key problem to be addressed is simply awareness of new informational products. Once awareness is increased, the computer market among physicians promises to grow even more rapidly.

For further information, contact Larry J. Freshnock, Ph.D., Director, Survey and Opinion Research, on (312) 645-4450.

• • •

Book on AMA History

Written by Frank C. Campion, *The AMA and U.S. Health Policy Since 1940* is an authorized history that offers behind-the-scene views of how the AMA and American medicine became politicized, of what triggered the founding of the American Medical Political Action Committee, of what happened inside the AMA after Medicare was enacted, and of how the AMA avoided financial collapse in 1974. The book is published by Chicago Review Press.

A former writer and editor of *Life* magazine, Campion has been on the AMA staff since 1970. *Booklist* says his history has several advantages over other books on the AMA, including timeliness and access to ample sources: "Anyone seeking information about or understanding of the AMA in the last 40 years will want this valuable book."

The illustrated and indexed book is in the Faculty Library and is available in bookstores at $25.

NIH Consensus Panel Issues Report Lowering Blood Cholesterol to Prevent Heart Disease

A National Institutes of Health (NIH) consensus development statement on lowering blood cholesterol to prevent heart disease now may be obtained from the NIH Office of Medical Applications of Research.

The report was prepared by a panel of experts, who considered scientific evidence presented at a consensus development conference at the NIH. It contains recommendations and conclusions concerning lowering blood cholesterol to prevent heart disease.

At NIH, consensus conferences bring together researchers, practicing physicians, representatives of public interest groups, consumers, and others to carry out scientific assessments of drugs, devices, and procedures in an effort to evaluate their safety and effectiveness.

Free, single copies of the consensus statement on lowering blood cholesterol to prevent heart disease are available from

Michael J. Bernstein
Office of Medical Applications of Research
National Institutes of Health
Building 1, Room 216
Bethesda, MD 20205

Consultation

The Faculty's radio program on WBJC-FM (91.5 mHz on your dial) is on the air between 10 and 11 a.m. on alternate Wednesdays

September 4	**Immunizations**	Robert Ancona MD
September 18	**How to be a Wise Consumer of Health Care**	Donald T. Lewers MD
October 2	**Osteoporosis**	Robert D. Katz MD
October 16	**Pain, How to Stand It**	Nelson Hendler MD
October 30	**AIDS**	Frank Polk MD

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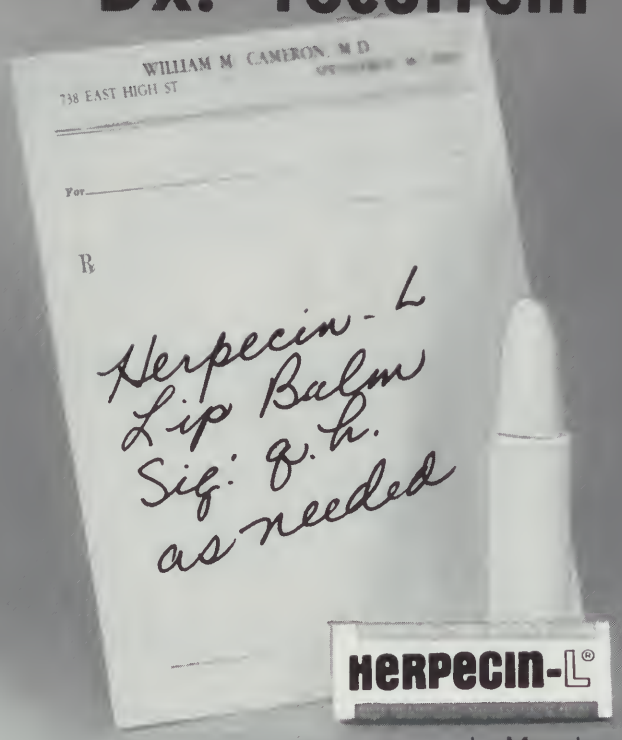
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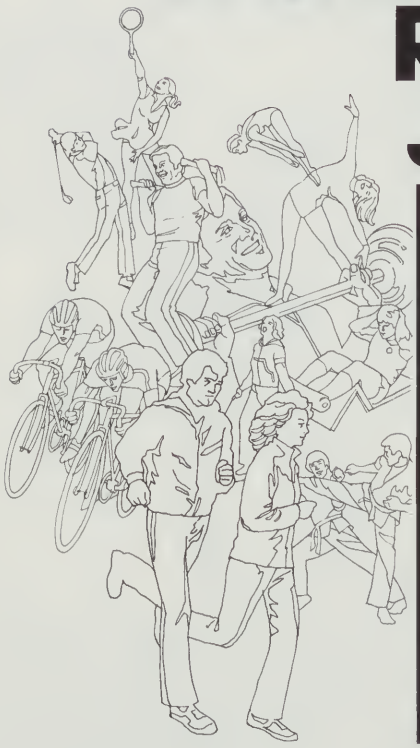
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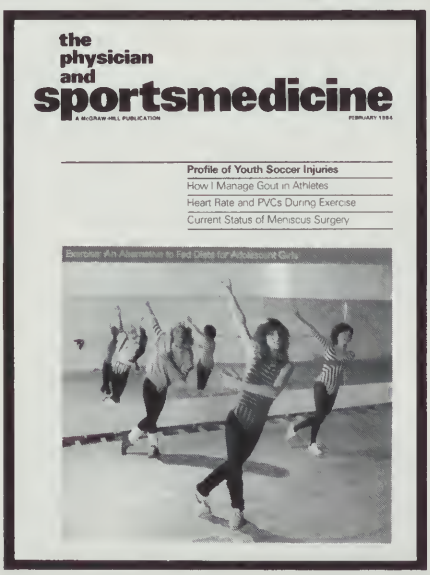
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Your Medical Faculty at Work

The Executive Committee at its session held Thursday, May 23, 1985, established an Ad Hoc Committee on the role of Corporations in the Delivery of Health Care. Chaired by President-elect Donald T. Lewers MD, of Easton, the Committee will make a report to the Council as to what actions, if any, the Faculty should take in this regard.

In other actions, the group approved communicating with various state agencies to offer Faculty assistance in the various recommendations from the Governor's Task Force on Health Care Cost Containment. About six recommendations of this Task Force are pending.

Staff was instructed to prepare a report and recommendation, if any, to the Council or Executive Committee in connection with payment arrangements for low-income Medicare beneficiaries. It declined, at this time, to provide financial assistance to a physician in his potential suit against a hospital for nonrenewal of privileges. Approval was given for voluntary dismissal of the suit against Nurse Practitioner regulations that permit such individuals to prescribe drugs.

Legal Counsel was instructed that formal opinions should not be rendered to Specialty or Component Societies who have been requesting such opinions. Informal opinions will continue to be given.

Referred to Legal Counsel was a proposal by an attorney to a group of Montgomery County physicians in connection with legal action to increase the conversion factor in Workmen's Compensation cases.

The Faculty's Educational, Charitable and Research Foundation, whose Executive Committee is composed of members of the Faculty's Executive Committee, approved a resolution dedicating funds from the Estate of Russell S. Fisher MD for building purposes. It also approved this Foundation acting as a recipient and disburser of funds for a proposed Pakistan/Afghanistan medical relief program being developed by a Charles County physician.

JOHN SARGEANT CAE
Executive Director

Medical Miscellany

Dear Health Care Provider:

I have become aware that a conversion provision in State regulations makes it illegal for an insurer to refuse to allow a chronically ill or handicapped person an individual policy without evidence of insurability if that person has been covered by a group policy for at least three months and whose coverage is terminated for any reason other than failure of the insured person to pay a required premium. An individual has 60 days from the termination of coverage under the group policy to convert.

This regulation is not well publicized or known by insurers or those seeking insurance. It appears that the best way of disseminating this information to those who are affected is by asking organizations such as yours to publicize the information. For this reason, I refer you to the conversion privilege regulation [COMAR 09.30.61 Conversion or Continuation of Group Health Insurance] and ask you to use your resources to see that the people who could benefit from it have access to the information.

Should anyone encounter any difficulty in obtaining a policy that meets these requirements, contact the office of the Insurance Commissioner (659-6184) for assistance.

LAURENCE LEVITAN, **Chairman**
Budget and Taxation Committee
State of Maryland

Photo Contest 1985

The Fifth Annual Photo Contest received enthusiastic support with twenty-two Faculty and Auxiliary members entering a total of forty-six photographs in the black-and-white and color categories.

The judges this year were Michele Elliott, former Assistant Director for the Dalsheimer Gallery on Charles Street in Baltimore and Ed Wortek, instructor of photography at Goucher College. The winners for 1985 were Erwin Bacmeister MD, first place, color category; Patricia Pidlaoan (Auxiliary Member), second place, color category; and Laurence Rubin MD, first and second places, black-and-white category. Gift certificates from the Dalsheimer Gallery were presented to the winners before the House of Delegates at the 1985 Annual Meeting.

Unfortunately, contest entrants were disappointed this year to learn that the traditional display of all submitted photos at the Annual Meeting had to be cancelled. A last-minute ruling by the Baltimore County Fire Marshall prohibited Med-Chi from exhibiting the photographs at Hunt Valley. "This year's array of photographs were particularly impressive," said Med-Chi's Public Relations Chairman, James E. Bell MD, "and the lack of a display was certainly regrettable. The 1986 Annual Meeting, however, will take place in the spacious Baltimore Convention Center," he continued, "and we can be assured of a splendid display of all photographs entered next year. Winners of the 1985 Photo Contest also will be on display at that time."

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AUGUST 1985

REVISION OF THE CASE DEFINITION OF ACQUIRED IMMUNODEFICIENCY SYNDROME FOR NATIONAL REPORTING--UNITED STATES

Issues related to the case definition of AIDS were discussed by the Conference of State and Territorial Epidemiologists (CSTE) at its annual meeting in Madison, Wisconsin, June 2-5, 1985. The CSTE approved the following resolutions:

1. that the case definition of AIDS used for national reporting continue to include only the more severe manifestations of HTLV-III/LAV infection; and

2. that CDC develop more inclusive definitions and classifications of HTLV-III/LAV infection for diagnosis, treatment, and prevention, as well as for epidemiologic studies and special surveys; and

3. that the following refinements be adopted in the case definition of AIDS used for national reporting:

   a. In the absence of the opportunistic diseases required by the current case defintion, any of the following diseases will be considered indicative of AIDS if the patient has a positive serologic or virologic test for HTLV-III/LAV:

      (1) disseminated histoplasmosis (not confined to lungs or lymph nodes), diagnosed by culture, histology, or antigen detection;

      (2) isosporiasis, causing chronic diarrhea (over 1 month), diagnosed by histology or stool microscopy;

(3) bronchial or pulmonary candidiasis, diagnosed by microscopy or by presence of characteristic white plaques grossly on the bronchial mucosa (not by culture alone).

(4) non-Hodgkin's lymphoma of high-grade pathologic type (diffuse, undifferentiated) and of B-cell or unknown immunologic phenotype, diagnosed by biopsy;

(5) histologically confirmed Kaposi's sarcoma in patients who are 60 years old or older when diagnosed.

b. In the absence of the opportunistic diseases required by the current case definition, a histologically confirmed diagnosis of chronic lymphoid interstitial pneumonitis in a child (under 13 years of age) will be considered indicative of AIDS unless test(s) for HTLV-III/LAV are negative.

c. Patients who have a lymphoreticular malginancy diagnosed more than 3 months after the diagnosis of an opportunistic disease used as a marker for AIDS will no longer be excluded as AIDS cases.

d. To increase the specificity of the case definition, patients will be excluded as AIDS cases if they have a negative result on testing for serum antibody to HTLV-III LAV, have no other type of HTLV-III/LAV test with a positive result, and do not have a low number of T-helper lymphocytes or a low ratio of T-helper to T-suppressor lymphocytes. In the absence of test results, patients satisfying all other criteria in the definition will continue to be included.

CDC will immediately adopt the above amendments to the case definition of AIDS for national reporting. This revision in the case definition will result in the reclassification of less than 1% of cases previously reported to CDC. The number of additional new cases reportable as a result of the revision is expected to be small. Cases included under the revised definition will be distinguishable from cases included under the old defintion so as to provide a consistent basis for interpretation of trends. CDC will also develop draft classifications for disease manifestations of HTLV-III/LAV infections other than AIDS, distribute these widely for comment, and publish the results.

Adapted from the Centers for Disease Control (CDC), Morbidity and Mortality Weekly Report, June 28, 1985/Vol. 34/No. 25.
References available upon request from CDC.

Gonozyme™

1. The Gonozyme test is a solid phase enzyme immunoassay for the detection of gonococcal antigen. Because Gonozyme test results are unaffected by transit conditions (time, temperature, etc.), its primary value is for situations where unfavorable transit conditions are contributing to culture deficiencies. Once at the site of processing, Gonozyme test results are available in 4-5 hours. Gonozyme also can detect vancomycin-sensitive specimens that might be missed by using selective medium culture.

2. According to current published data, Gonozyme results with male urethritis specimens have the high sensitivity and specificity associated with urethral Gram stained smears and selective medium cultures. However, because Gram stain tests can be performed immediately and Gonozyme results are not immediately available, Gonozyme should not be the principal diagnostic test used for men. If testing in addition to Gram stain is desired, either Gonozyme or culture may be used. If transport factors are deficient, Gonozyme is favored. If PPNG or chromosomally mediated resistance is a significant concern, a culture should be used.

3. The published data show that Gonozyme appears less sensitive and less specific than selective medium culture of cervical specimens from women at high risk of having gonorrhea. In addition, the manufacturer recommends that a positive Gonozyme test be confirmed by appropriate methods, including culture and, if indicated, by carbohydrate (sugar) utilization, which requires the viable organisms that a culture is able to provide. Therefore, Gonozyme currently offers no advantage in testing women in an STD clinic beyond the promptness which the initial testing results are available compared with the selective media culture.

4. Data shows that the predictive value of a positive test is approximately 50 percent when Gonozyme is used to test women in populations of low gonorrhea prevalence. Therefore, it is particularly important that a positive Gonozyme test result in these women be confirmed by culture. Based on clinician judgement, treatment could be initiated while awaiting confirmatory culture results.

5. Gonozyme is not recommended for rectal or pharyngeal specimens, for test-of-cure in either men or women, in medicolegal situations, if resistance is to be detected, or if other antimicrobial testing is needed.

SOURCE: Centers for Disease Control, References are available upon request.

DIVISION OF VETERINARY MEDICINE

LABORATORY CONFIRMED ANIMAL RABIES CASES IN MARYLAND

1983 - 1985 through 7/15/1985

Counties	Total Cases 1983	1984	To Date 1985	Bat	Bovine	Cat	Dog	Fox	Ground Hog	Raccoon	Skunk	Other
Allegany	22	3	4							4		
Anne Arundel	9	46	29					1		28		
Baltimore	3	54	129	1	1			8	1	118		
Calvert		1	14							14		
Caroline		1										
Carroll	5	148	64		1	5			1	57		
Cecil	1	1										
Charles	3	7	17					1		16		
Dorchester												
Frederick	192-	247	33	3	1	2				26	1	
Garrett	18	23	8						1	7		
Harford	2											
Howard	29	175	26					1		24		1-hor
Kent												
Montgomery	434	119	17	3				1		12		1-sq.
Prince George's	16	239	58	1		1		1		54		1-op.
Queen Anne's												
St. Mary's	3		8							8		
Somerset												
Talbot	1											
Washington	98	30	5	3						2		
Wicomico												
Worcester												
Baltimore City	2	5	5							5		
TOTALS	838	1100	417	11	3	8		13	3	375	1	3
Totals last year thru 7/15/84			623	15	2	4		12	4	570	14	2

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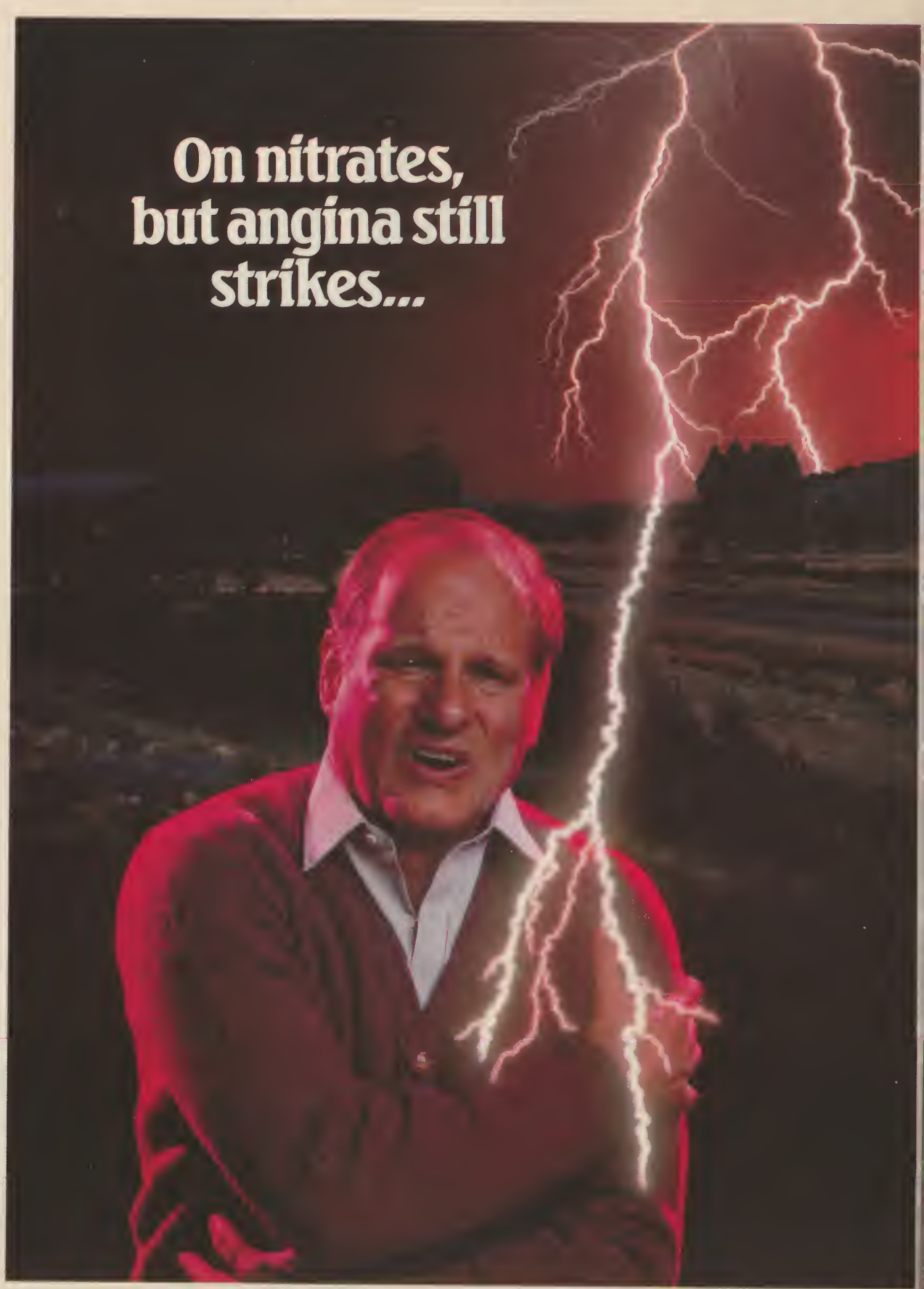
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J-5491 June 1985


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Cardiovascular contraindications to the use of Isoptin are similar to those of beta blockers: severe left ventricular dysfunction, hypotension (systolic pressure <90 mm Hg) or cardiogenic shock, sick sinus syndrome (if no artificial pacemaker is present) and second- or third-degree AV block.

So, the next time a nitrate is not enough, add Isoptin... for more comprehensive antianginal protection without side effects which may cramp an active life style.



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Please see brief summary on following page.

ISOPTIN®
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Contraindications: Severe left ventricular dysfunction (see *Warnings),* hypotension (systolic pressure < 90 mm Hg) or cardiogenic shock, sick sinus syndrome (except in patients with a functioning artificial ventricular pacemaker), 2nd- or 3rd-degree AV block. **Warnings:** ISOPTIN should be avoided in patients with severe left ventricular dysfunction (e.g., ejection fraction < 30% or moderate to severe symptoms of cardiac failure) and in patients with any degree of ventricular dysfunction if they are receiving a beta blocker. (See *Precautions.)* Patients with milder ventricular dysfunction should, if possible, be controlled with optimum doses of digitalis and/or diuretics before ISOPTIN is used. (Note interactions with digoxin under *Precautions.*) ISOPTIN may occasionally produce hypotension (usually asymptomatic, orthostatic, mild and controlled by decrease in ISOPTIN dose). Elevations of transaminases with and without concomitant elevations in alkaline phosphatase and bilirubin have been reported. Such elevations may disappear even with continued treatment; however, four cases of hepatocellular injury by verapamil have been proven by rechallenge. Periodic monitoring of liver function is prudent during verapamil therapy. Patients with atrial flutter or fibrillation and an accessory AV pathway (e.g. W-P-W or L-G-L syndromes) may develop increased antegrade conduction across the aberrant pathway bypassing the AV node, producing a very rapid ventricular response after receiving ISOPTIN (or digitalis). Treatment is usually D.C.-cardioversion, which has been used safely and effectively after ISOPTIN. Because of verapamil's effect on AV conduction and the SA node, 1° AV block and transient bradycardia may occur. High grade block, however, has been infrequently observed. Marked 1° or progressive 2° or 3° AV block requires a dosage reduction or, rarely, discontinuation and institution of appropriate therapy depending upon the clinical situation. Patients with hypertrophic cardiomyopathy (IHSS) received verapamil in doses up to 720 mg/day. It must be appreciated that this group of patients had a serious disease with a high mortality rate and that most were refractory or intolerant to propranolol. A variety of serious adverse effects were seen in this group of patients including sinus bradycardia, 2° AV block, sinus arrest, pulmonary edema and/or severe hypotension. Most adverse effects responded well to dose reduction and only rarely was verapamil discontinued. **Precautions:** ISOPTIN should be given cautiously to patients with impaired hepatic function (in severe dysfunction use about 30% of the normal dose) or impaired renal function, and patients should be monitored for abnormal prolongation of the PR interval or other signs of excessive pharmacologic effects. Studies in a small number of patients suggest that concomitant use of ISOPTIN and beta blockers may be beneficial in patients with chronic stable angina. Combined therapy can also have adverse effects on cardiac function. Therefore, until further studies are completed, ISOPTIN should be used alone, if possible. If combined therapy is used, close surveillance of vital signs and clinical status should be carried out. Combined therapy with ISOPTIN and propranolol should usually be avoided in patients with AV conduction abnormalities and/or depressed left ventricular function. Chronic ISOPTIN treatment increases serum digoxin levels by 50% to 70% during the first week of therapy, which can result in digitalis toxicity. The digoxin dose should be reduced when ISOPTIN is given, and the patients should be carefully monitored to avoid over- or under-digitalization. ISOPTIN may have an additive effect on lowering blood pressure in patients receiving oral antihypertensive agents. Disopyramide should not be given within 48 hours before or 24 hours after ISOPTIN administration. Until further data are obtained, combined ISOPTIN and quinidine therapy in patients with hypertrophic cardiomyopathy should probably be avoided, since significant hypotension may result. Clinical experience with the concomitant use of ISOPTIN and short- and long-acting nitrates suggest beneficial interaction without undesirable drug interactions. Adequate animal carcinogenicity studies have not been performed. One study in rats did not suggest a tumorigenic potential, and verapamil was not mutagenic in the Ames test. *Pregnancy Category C*: There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy, labor and delivery only if clearly needed. It is not known whether verapamil is excreted in breast milk; therefore, nursing should be discontinued during ISOPTIN use. **Adverse Reactions:** Hypotension (2.9%), peripheral edema (1.7%), AV block: 3rd degree (0.8%), bradycardia: HR < 50/min (1.1%), CHF or pulmonary edema (0.9%), dizziness (3.6%), headache (1.8%), fatigue (1.1%), constipation (6.3%), nausea (1.6%), elevations of liver enzymes have been reported. (See *Warnings.*) The following reactions, reported in less than 0.5%, occurred under circumstances where a causal relationship is not certain: ecchymosis, bruising, gynecomastia, psychotic symptoms, confusion, paresthesia, insomnia, somnolence, equilibrium disorder, blurred vision, syncope, muscle cramp, shakiness, claudication, hair loss, macules, spotty menstruation. **How Supplied:** ISOPTIN (verapamil HCl) is supplied in round, scored, film-coated tablets containing either 80 mg or 120 mg of verapamil hydrochloride and embossed with "ISOPTIN 80" or "ISOPTIN 120" on one side and with "KNOLL" on the reverse side. Revised August, 1984. 2385

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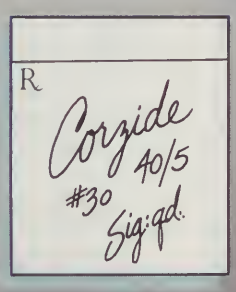
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*Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure. The 1984 report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure. Arch Intern Med 144:1045-1057, 1984.

Please see brief summary of prescribing information on following page

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CORZIDE® 40/5
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Nadolol-Bendroflumethiazide Tablets

DESCRIPTION: CORZIDE (Nadolol-Bendroflumethiazide Tablets) for oral administration combines two antihypertensive agents: CORGARD® (nadolol), a nonselective beta-adrenergic blocking agent, and NATURETIN® (bendroflumethiazide), a thiazide diuretic-antihypertensive. Formulations: 40 mg and 80 mg nadolol oer tablet combined with 5 mg bendroflumethiazide.

CONTRAINDICATIONS: Nadolol — Bronchial asthma, sinus bradycardia and greater than first degree conduction block, cardiogenic shock, and overt cardiac failure (see WARNINGS). **Bendroflumethiazide** — Anuria, and in those with previous hypersensitivity to bendroflumethiazide or other sulfonamide-derived drugs.

WARNINGS: Nadolol — Cardiac Failure — Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta-blockade may precipitate more severe failure. Although beta-blockers should be avoided in overt congestive heart failure, if necessary, they can be used with caution in patients with a history of failure who are well compensated, usually with digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle. IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta-blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, digitalize and/or give diuretics, and closely observe response, or discontinue nadolol (gradually, if possible).

Exacerbation of Ischemic Heart Disease Following Abrupt Withdrawal — Hypersensitivity to catecholamines has been observed in patients withdrawn from beta-blocker therapy; exacerbation of angina and, in some cases, myocardial infarction have occurred after *abrupt* discontinuation of such therapy. When discontinuing chronic use of nadolol, particularly in patients with ischemic heart disease, gradually reduce dosage over a 1- to 2-week period and carefully monitor the patient. Reinstitute nadolol promptly (at least temporarily) and take other measures appropriate for management of unstable angina if angina markedly worsens or acute coronary insufficiency develops. Warn patients not to interrupt or discontinue therapy without physician's advice. Because coronary artery disease is common and may be unrecognized, it may be prudent not to discontinue nadolol therapy abruptly even in patients treated only for hypertension.

Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema) — PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA-BLOCKERS. Administer nadolol with caution since it may block bronchodilation produced by endogenous or exogenous catecholamine stimulation of beta$_2$ receptors. **Major Surgery** — Because beta blockade impairs the ability of the heart to respond to reflex stimuli and may increase the risks of general anesthesia and surgical procedures, resulting in protracted hypotension or low cardiac output, it has generally been suggested that such therapy should be withdrawn several days prior to surgery. Recognition of the increased sensitivity to catecholamines of patients recently withdrawn from beta-blocker therapy, however, has made this recommendation controversial. If possible, withdraw beta-blockers well before surgery takes place. In emergency surgery, inform the anesthesiologist that the patient is on beta-blocker therapy. Use of beta-receptor agonists such as isoproterenol, dopamine, dobutamine, or levarterenol can reverse the effects of nadolol. Difficulty in restarting and maintaining the heart beat has also been reported with beta-adrenergic receptor blocking agents. **Diabetes and Hypoglycemia** — Beta-adrenergic blockade may prevent the appearance of premonitory signs and symptoms (e.g., tachycardia and blood pressure changes) of acute hypoglycemia. This is especially important with labile diabetics. Beta-blockade also reduces release of insulin in response to hyperglycemia; therefore, it may be necessary to adjust dose of antidiabetic drugs. **Thyrotoxicosis** — Beta-adrenergic blockade may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism. To avoid abrupt withdrawal of beta-adrenergic blockade which might precipitate a thyroid storm, carefully manage patients suspected of developing thyrotoxicosis.

Bendroflumethiazide — Use with caution in severe renal disease. In patients with renal disease, azotemia may be precipitated. With impaired renal function, effects of the drug may be cumulative. Use with caution in impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma. Sensitivity reactions may occur in patients with a history of allergy or bronchial asthma. Possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

PRECAUTIONS: General — Nadolol — Use with caution in patients with impaired hepatic or renal function (see DOSAGE AND ADMINISTRATION).

Bendroflumethiazide — At appropriate intervals, perform serum electrolytes determination to detect possible electrolyte imbalance warning signs of which are dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and G.I. disturbances such as nausea and vomiting. Observe patients for clinical signs of fluid or electrolyte imbalance; namely, hyponatremia, hypochloremic alkalosis, hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Drugs such as digitalis may influence serum electrolytes. Hypokalemia may develop, especially with brisk diuresis, in presence of severe cirrhosis. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Response of the heart to toxic effects of digitalis can be exaggerated with hypokalemia. Use potassium supplements such as high potassium foods to avoid or treat hypokalemia. Any chloride deficit is generally mild and usually does not require specific therapy except under extraordinary circumstances (as in liver or renal disease). Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction rather than salt administration except in rare instances when the hyponatremia is life threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain thiazide-treated patients. Latent diabetes mellitus may become manifest during thiazide therapy. Antihypertensive effects of bendroflumethiazide may be enhanced in the postsympathectomy patient.

Careful reappraisal of therapy and consideration given to withholding or stopping diuretic therapy is necessary if rising nonprotein nitrogen or BUN (indicative of progressive renal impairment) occurs. Thiazides may decrease serum PBI levels without signs of thyroid disturbance. Thiazides decrease calcium excretion. Pathologic changes in parathyroid gland with hypercalcemia and hypophosphatemia have been occasionally observed with prolonged therapy. Common complications of hyperparathyroidism have not been seen.

Information for Patients — Warn patients, especially those with evidence of coronary arter... insufficiency, against interruption or discontinuation of nadolol without physician's advice. Although cardiac failure rarely occurs in properly selected patients, advise patients being treated with beta-adrenergic blocking agents to consult physician at the first sign or symptom of impending failure. Advise patients of proper course if dose inadvertently missed.

Laboratory Tests — Regularly monitor serum and urine electrolyte levels (see WARNINGS, *Bendroflumethiazide*, and PRECAUTIONS, *General, Bendroflumethiazide).*

Drug Interactions — Nadolol — When administered concurrently the following drugs may interact with beta-adrenergic blocking agents: **Anesthetics, general** — exaggeration of anesthetic-induced hypotension (see WARNINGS, *Nadolol, Major Surgery).* **Antidiabetic drugs (oral agents and insulin)** — hypoglycemia or hyperglycemia; adjust antidiabetic drug dosage accordingly (see WARNINGS, *Nadolol, Diabetes and Hypoglycemia).* **Catecholamine-depleting drugs (e.g., reserpine)** — additive effect; monitor closely for evidence of hypotension and/or excessive bradycardia.

Bendroflumethiazide — When administered concurrently the following drugs may interact with thiazide diuretics: **Alcohol, barbiturates, or narcotics** — may potentiate orthostatic hypotension. **Antidiabetic drugs (oral agents and insulin)** — thiazide-induced hyperglycemia may require adjustment of antidiabetic drug dosage. **Other antihypertensive drugs** — additive or potentiated effect. **Corticosteroids, ACTH** — intensified electrolyte depletion, particularly hypokalemia. **Ganglionic or peripheral adrenergic blocking drugs** — potentiated effect. **Preanesthetic and anesthetic agents** — effects may be potentiated; adjust dosage accordingly. **Pressor amines (e.g., norepinephrine)** — possible decreased response but not sufficient to preclude their use. **Skeletal muscle relaxants, nondepolarizing (e.g., tubocurarine)** — possible increased response.

Drug/Laboratory Test Interactions — Discontinue thiazides before tests for parathyroid function (see PRECAUTIONS, *General, Bendroflumethiazide).*

Carcinogenesis, Mutagenesis, Impairment of Fertility — Nadolol — In 1 to 2 years oral toxicologic studies in mice, rats, and dogs, nadolol did not produce significant toxic effects. In 2-year oral carcinogenic studies in rats and mice, nadolol did not produce neoplastic, preneoplastic, or nonneoplastic pathologic lesions. **Bendroflumethiazide** — Long-term studies in animals have not been performed.

Pregnancy — Teratogenic Effects — Nadolol — Category C. In animal reproduction studies with nadolol, evidence of embryo- and fetotoxicity was found in rabbits, but not in rat or hamsters, at doses 5 to 10 times greater (on a mg/kg basis) than the maximum indicated human dose; no teratogenic potential was seen in any of these species. There are no well-controlled studies in pregnant women; therefore, use nadolol in pregnant women only if potential benefit justifies potential risk to the fetus. **Bendroflumethiazide** — Category C. Animal reproduction studies have not been conducted. This drug's effect on the fetus when administered to a pregnant woman or its effect on reproductive capacity is not known. Bendroflumethiazide should be given to a pregnant woman only if clearly needed. **Nonteratogenic Effects** — Since thiazides cross the placental barrier and appear in cord blood, weigh anticipated benefit of the drug in pregnant women against possible hazards to the fetus; these hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other reactions which have occurred in adults.

Nursing Mothers — Both nadolol and bendroflumethiazide are excreted in human milk. Because of the potential for serious adverse reactions in nursing infants either discontinue nursing or discontinue therapy, taking into account the importance of CORZIDE (Nadolol-Bendroflumethiazide Tablets) to the mother.

Pediatric Use — Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Nadolol — Most adverse effects have been mild and transient and have rarely required nadolol withdrawal. **Cardiovascular** — Bradycardia with heart rates less than 60 beats per minute occurs commonly, and heart rates below 40 beats per minute and/or symptomatic bradycardia were seen in about 2 of 100 patients. Symptoms of peripheral vascular insufficiency, usually of the Raynaud type, have occurred in approximately 2 of 100 patients. Cardiac failure, hypotension, and rhythm/conduction disturbances have each occurred in about 1 of 100 patients. Single instances of first degree and third degree heart block have been reported; intensification of AV block is a known effect of beta-blockers (see also CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS). **Central Nervous System** — Dizziness or fatigue reported in approximately 2 of 100 patients; paresthesias, sedation, and change in behavior reported in approximately 6 of 1000 patients. **Respiratory** — Bronchospasm reported in approximately 1 of 1000 patients (see CONTRAINDICATIONS and WARNINGS). **Gastrointestinal** — Nausea, diarrhea, abdominal discomfort, constipation, vomiting, indigestion, anorexia, bloating, and flatulence each reported in 1 to 5 of 1000 patients. **Miscellaneous** — Each of the following reported in 1 to 5 of 1000 patients: rash; pruritus; headache; dry mouth, eyes, or skin; impotence or decreased libido; facial swelling; weight gain; slurred speech; cough; nasal stuffiness; sweating; tinnitus; blurred vision. Although relationship to drug usage is not clear, sleep disturbances have been reported. The oculomucocutaneous syndrome associated with practolol has not been reported with nadolol. The following adverse reactions may also occur: **Central Nervous System** — reversible mental depression progressing to catatonia; visual disturbance; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss; emotional lability with slightly clouded sensorium, decreased performance on neuropsychometrics. **Gastrointestinal** — mesenteric arterial thrombosis; ischemic colitis. **Hematologic** — agranulocytosis; thrombocytopenic or nonthrombocytopenic purpura. **Allergic** — fever combined with aching and sore throat; laryngospasm; respiratory distress. **Miscellaneous** — reversible alopecia; Peyronie's disease; erythematous rash; arterial insufficiency.

Bendroflumethiazide — Gastrointestinal System — anorexia, gastric irritation, nausea, vomiting, cramping, diarrhea, constipation, jaundice (intrahepatic cholestatic jaundice), pancreatitis. **Central Nervous System** — dizziness, vertigo, paresthesia, headache, xanthopsia. **Hematologic** — leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia. **Dermatologic-Hypersensitivity** — purpura, photosensitivity, rash, urticaria, necrotizing angiitis (vasculitis, cutaneous vasculitis). **Cardiovascular** — orthostatic hypotension may occur. **Other** — hyperglycemia, glycosuria, occasional metabolic acidosis in diabetics; hyperuricemia, allergic glomerulonephritis, muscle spasm, weakness, restlessness. Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy withdrawn.

OVERDOSAGE: Nadolol may cause excessive bradycardia, cardiac failure, hypotension, bronchospasm if overdosed. Overdosage of thiazides may cause lethargy, which may progress to coma within a few hours, with minimal depression of respiration and cardiovascular function and without evidence of serum electrolyte changes or dehydration. Gastrointestinal irritation and hypermotility may occur. Transitory increase in BUN and serum electrolyte changes may occur, especially in patients with renal impairment.

Treatment — Nadolol can be removed from the general circulation by hemodialysis. In determining duration of corrective therapy, take note of the long duration of the effect of nadolol. In addition to gastric lavage, employ the following measures, as appropriate. **Excessive Bradycardia** — Administer atropine (0.25 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously. **Cardiac Failure** — Administer a digitalis glycoside and diuretic. It has been reported that glucagon may also be useful in this situation. **Hypotension** — Administer vasopressors, e.g., epinephrine or levarterenol. (There is evidence that epinephrine may be the drug of choice.) **Bronchospasm** — Administer a beta$_2$ stimulating agent and/or a theophylline derivative. **Stupor or Coma** — Supportive therapy is warranted. **Gastrointestinal Effects** — Symptomatic treatment as needed. **BUN and/or Serum Electrolyte Abnormalities** — Institute supportive measures as required to maintain hydration, electrolyte balance, respiration, and cardiovascular and renal function.

DOSAGE AND ADMINISTRATION: DOSAGE MUST BE INDIVIDUALIZED. Patients with renal failure require adjustment in dosing interval; see package insert for dosage in these patients.

Consult package insert before prescribing CORZIDE (Nadolol-Bendroflumethiazide Tablets).

HOW SUPPLIED: Available as scored tablets containing 40 mg nadolol combined with 5 mg bendroflumethiazide and 80 mg nadolol combined with 5 mg bendroflumethiazide in bottles of 10

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505-502 Issued: March 1985

Med-Chi's 125th President: J.D. Drinkard MD

You were elected president of Med-Chi at the Annual Meeting in April. Now four months into your year's tenure, what are your thoughts on the office and its duties?

I knew it would be a trying year, but I was not intellectually or emotionally prepared for the responsibility that goes with the job. I served on a number of committees in my own county medical society and here at Med-Chi, but the transition to being spokesman for the 7,000 physician-members of Med-Chi is a challenge and an awesome responsibility. This is especially true now when one must be informed about so many issues affecting the socioeconomics of medicine. Concurrently, one must examine the possible ramifications of these issues on quality care for our patients.

What is the major concern of your constituents, the physicians of Maryland?

I believe the primary mandate of the physicians who elected me is assurance of the highest standard of care possible for every patient. A secondary mandate is to represent the physicians' perspective on how that may be attained.

There are rumors of discontent with Med-Chi as an organization and with its policies. However, we notice that membership is growing. How do you explain this?

A number of factors are involved in the discontent of physicians; most of these can be expressed in one word, CHANGE. The change is coming so rapidly that most physicians are severely taxed to adapt. Some of this change is healthy for both physicians and patients, but from our perspective, it seems much change is designed by health planners or bureaucrats with no consideration of either patients or physicians. Patients are changing: they question proved scientific methods of diagnosis and treatment.

Competition is changing medical practice. This comes from prepaid plans and from physicians who engage in advertising.

Hospitals and insurance companies are potential adversaries.

Politicians seem bent on destroying the most efficient and highest quality health care system in the world by setting fees, increasing the supply of "health care providers," and licensing and expanding the "duties" of just about everyone who used to work under competent supervision. Hospitals seem to be on a collision course with those same physicians who have kept them supplied with patients.

What are physicians asking of Med-Chi?

Most say "DO SOMETHING." Some understand that we have to operate under the constraints of law. Some want to form a labor union. Others seem angry over their disillusionment at rational decisions being taken away from them and relegated to a formula that clumps all diagnoses into a DRG. I agree; these are the same concerns I have. And they are being raised by intelligent men and women who have feeling for the welfare of sick people that transcends considerations of saving a few dollars.

What are they asking of Med-Chi? Physicians are asking us to listen and to reflect their concern where it will do the most good. They are asking us to become as litigious as our adversaries. They are asking us to get government off their backs and to slow down the mandated changes lest we throw out the baby with the bath water. We are doing that as best we can, but physicians want more immediate results. I do too, but diplomacy has to be titrated with power, and the power has to be used when it will do the most good. We are not the first to turn a seeming defeat into a win, and I predict we will do just that.

Goals

Each new president assumes office with special goals for the Faculty. What are yours?

My first goal is to improve the democracy of Med-Chi. We are far ahead of other states in that regard, but that should not obscure our vigilance of ourselves. Some factions within any organization are healthy when they serve the purpose of promoting debate and a degree of dissension, but we have to avoid significant decision making beyond debate of any member.

I would like to see more enrollment and participation of women in the Faculty. They should be valued and respected members of our profession and the Faculty. I demonstrated this in my appointments.

I want to bring the Auxiliary closer to the daily business of the Faculty. Many members don't seem to recognize the spouses' organization as a valuable asset. I also would like to see more husbands join the Auxilliary.

I want Med-Chi to assume a more personal role in the lives of its members and their families. I was glad this goal seemed to be shared by those who attended the program on Physicians and their Families at the Annual Meeting in April, but I view that program as just the beginning of Med-Chi's potential to help members and their families during crises of illness, physician disability, malpractice lawsuit, or death.

I want to offer computer literacy to every Faculty member. Members then can make an informed decision about the potential this technology may offer in practice or research. Council has approved preliminary steps for making our ad hoc group on computers in medicine a full committee. I will speak for this approval when it comes before the House of Delegates.

We have to encourage membership at all levels within Med-Chi. I hope our offer of council membership to the

I feel like Henry Kissinger when he was Secretary of State. He stepped into his plane and the pilot said, "Where to, Mr. Secretary?" Kissinger replied, "You can take me anywhere because wherever we go there is trouble that needs attention."

***J.D. DRINKARD* MD**
House of Delegates, April 27

deans of the medical schools will encourage their faculty members to join. I would like to see county and city societies launch a major campaign to enroll those practicing physicians who have benefited from our legislative, peer review, and other efforts. I suspect this may be easier as physicians begin to recognize the Faculty's major role in the changes that will take place in every practice in the near future.

What changes do you foresee in medical practice?

Social policy decisions are being made in medical practice without benefit of public debate. Voters should decide whether 10 to 12 percent of the gross national product is too much to spend on health care. This is done for every other budget item from defense to farm subsidies.

The key word for change in medical practice and total health care in this country is COST. In the early 1950s the government seduced hospitals and physicians with such plums as the Hill-Burton Act, medical school grants, student loans, and generous research grants. This built an excellent health care system and laid the ground for Medicare planning in the late 1950s.

In the early 1960s Medicare was legislated based on inaccurate actuarial studies (recently acknowledged), and the objections of organized medicine were presented by the media as opposition to medical care for senior citizens. (In truth, our opposition was to the very actuarial projections that recently were proved to be inaccurate.) We now have Medicare and Medicaid, and physicians who were treating the aged and poor for no fee are paid on a fee schedule that initially was "encouraged" but soon became mandated.

The Social Security Trust Fund looked good in the early 1960s, so politicians tapped it further to win favor from the electorate and began the disability program, black-lung program, and others. The initial intent was probably worthy and humanitarian, but subsequent liberalizing legislation along with cost-of-living adjustments and a high inflation rate have almost bankrupted the funds.

Hospitals and physicians must share the blame. Cost was not a significant consideration during the heyday of Medicare. Expensive testing and hospital days were a luxury all enjoyed; they were appreciated by both patients and their families. The first sign of trouble on the horizon came with PSROs. Remember how they were resented and called "cookbook medicine?" And we all said, "I told you so," when they didn't save any money.

Diagnosis related groupings (DRGs) and professional review organizations (PROs) were not a part of our vocabulary five years ago. After a "haphazard" trial in New Jersey, they were implemented nationwide in one form or another, and we were given a new worry: "What will happen if they apply DRGs to physicians' fees?" We might have had just that if we had not agreed to freeze fees for a year. In the midst of our efforts to control the professional cost of the Medicare bill, we were offered another option: Be a participating or nonparticipating physician this year, and if you are participating, you can raise your fees next year. That proved to be a false promise, and to add insult to injury, potential criminal and civil penalties were threatened. I have spoken only of Medicare because other insurance plans follow the Medicare lead.

With cost as the primary consideration let's look at what has happened and what probably will happen to medical practice in the near future. Industry has seen its cost of medical care rise rapidly, and labor has proved its willingness to bargain away more costly insurance programs in favor of job security or other fringe benefits. Increased copayments by indemnity health insurance policies are being imposed by competition among insurance companies and are driving young adults into the folds of HMOs or other prepaid insurance plans. These plans are being staffed by the oversupply of younger physicians. For-profit chains of hospitals, surgicenters, and similar enterprises are growing exponentially, threatening the stability of nonprofit hospitals, which still treat the most costly and chronic patients.

Physicians will be able to maintain private and autonomous practice only if they are willing to change their method of charging. Usual-and-customary changes as well as "blank checks" from insurers will soon become antiquated. The disparity in physician charges for procedure versus cognition has not escaped the attention of either insurance companies or regulatory government agencies. The give-and-take process will require equitable and good-faith negotiating from all of us. The alternative is to accept arbitrary price fixing. That is what DRG fees would mean.

A method of relative value scales has to be worked out, and it has to be done by physicians. There are antitrust problems, as proved by the recent ruling of

the Federal Trade Commission against the American Society of Internal Medicine, but I believe that Med-Chi can do it under the auspices of the Commission on Medical Discipline.

Your picture for the practicing physician's autonomy or income is not very encouraging, is it?

No, not for the immediate future, but I believe we will be heard and heeded if we stand by our convictions. Even though we sell a service that people don't want to buy, we are still the most trusted and admired profession. We have to make use of that.

• • •

J.D. Drinkard MD, a Towson psychiatrist, became the 125th elected president of the Medical and Chirurgical Faculty of the State of Maryland in April. Dr. Drinkard received the gavel of office at the closing session of the House of Delegates at the Faculty's Annual Meeting held at the Hunt Valley Inn.

A native of Virginia, Dr. Drinkard received his medical degree from the Medical College of Virginia. He served two years in the Naval Medical Service. He completed psychiatric residencies at Spring Grove State Hospital and the Sheppard and Enoch Pratt Hospital. After accepting a permanent position at Sheppard Pratt, he developed and directed the affiliation of the Department of Child Psychiatry with the Maryland Training School for Boys.

Today Dr. Drinkard is in the private practice of psychiatry and holds teaching and supervising appointments at the Sheppard and Enoch Pratt Hospital. He has been a consultant to the Social Security Administration, the Baltimore County Board of Education, Maryland Department of Juvenile Services, and the Maryland State Department of Education.

Dr. Drinkard has been an active member of the Baltimore County Medical Association, having served as president, and has taken a leadership role with program and ethics committees. He has served as a member of the Commission on Medical Discipline of the State of Maryland.

Long active in the movement toward integrated neighborhoods, Dr. Drinkard has lived in and been active on the Board of Directors of the Windsor Hills Association. He has participated in the Baltimore Neighborhoods and the National Neighbors organizations.



Incoming president **J. D. Drinkard** MD (right) receiving the presidential gavel from his predecessor, **George S. Malouf** MD.

Future Med-Chi Meetings

1985 Semiannual
September 1–8
Bermuda

1986 Annual
April 16–18
Baltimore Plaza Hotel

1986 Semiannual
September 10–14
Montreal

September 14–17
Post-Convention Trip
Chateau Frontenac
Quebec City

1987 Semiannual
Mid-September
Maui, Hawaii

1988 Semiannual
September 14–18
Bermuda

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Carroll Cty. (call collect) **730-2311**

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Remarks at the Presidential Banquet

Earlier today, as I passed the gavel to my good friend and successor, J.D. Drinkard MD, I felt the mixed emotions I'm sure all my predecessors have felt: a deep sense of pride in the outstanding dedication I've witnessed on the part of committee members, chairpersons, and others who have represented Med-Chi this past year. In addition to an overwhelming pride in the great accomplishments attained during the past year, I felt deep gratitude for the enormous contributions of our staff, our component Medical Societies, and our total membership.

A year ago, when I assumed the Presidency of Med-Chi, the main concern facing us was the escalating cost of medical care. I urged each of you to assume a leadership role in addressing this issue within your hospitals, your specialty societies, and, indeed, your own practice. Your positive response was even better than outstanding. More than 80 percent of our members accepted our call and that of AMA to voluntarily freeze fees.

However, this voluntary act on the part of physicians was followed closely by action of the federal government to freeze reimbursements under the Medicare program. The government's action was viewed by physicians as no reward for our noncompulsory step. But we shall persevere because we are the only group dedicated to people and their health needs. I therefore urge each of you to continue the strides we've begun and to become even more deeply involved in the cost issues within your hospitals and specialty societies.

As we continue to address this issue let us be ever vigilant that we not allow the pendulum to swing so far toward reducing costs as to challenge the quality and, indeed, to introduce the potential rationing of medical care.

We should keep constant in our minds the guiding principles that will keep us as we continue our journey through the morass of regulation and legislation to our goal of harmony of effort:

1. The patient should never be deprived of the freedom of choice in his or her selection of the physician.

2. We cannot accept rationing of medical care. We are a government of the people. The inalienable right of each citizen must not be altered in any attempt to reduce costs. Whenever there is a real need for care, it must be rendered. The gate for better health and the highest quality of life should have no gatekeeper.

3. Research and medical education should continue with the same momentum. We cannot hamper future discoveries because of temporary shortsightedness. The explosion of scientific breakthroughs in medicine during the past fifty years has elevated our profession to one of the highest scientific levels of performance, which we must apply with the highest levels of the "art of medical practice."

When I graduated from medical school, some of my peers believed that medicine had come its full distance and that there was no reason to expect more than possible marginal changes in the years ahead. We thought we knew it all! We soon discovered means of killing bacteria without affecting the cells of the host. Later, we began to understand the underlying cellular mechanisms of cancer. We are now transplanting organs and implanting devices, all toward improving and prolonging the high quality of life.

A long list of unsolved diseases remains on our agenda. The marvels of discoveries yet to come will be even more astonishing than those you and I have witnessed in our time.

We must not slow down new discoveries for disease prevention, and we will not slow down the proliferation of medical solutions, the implementation of which will add to the quality of life.

4. We cannot bargain away the quality of medical care rendered for any reason: governmental pressure for cost reductions, hospital pressures for reduced care, or the monetary concerns of business and industry, who look only at their bottom lines with little, if any, concern about their employees' quality of life. We must resist this pressure and never compromise on quality.

What we do in this time of crisis will be viewed by future generations of our children and our colleagues. Let us work together, now, for their benefit later.

To say that I am personally touched by your presence here is an understatement. I quite frankly will miss all of you so much. It has been a pleasure working with you and it will remain a pleasure to remember that pleasure.

GEORGE S. MALOUF **MD**
Immediate Past President

Annual Reports of Committees

Medical and Chirurgical Faculty of the State of Maryland

Minutes, House of Delegates First Meeting 763
Minutes, House of Delegates Second Meeting 773
Ad Hoc Building 776
Alcoholism 776
American Medical Association—Education and Research Foundation 777
Auxiliary 777
Bylaws 778
Continuing Medical Education Review 778
Council 779
Curator 780
Delegates to the AMA House of Delegates 780
Drugs 783
Emergency Medical Services 783
Emotional Health 784
Executive Director 784
Finance 784
Finney Fund 785
Health Planning and Manpower 785
Hospital Medical Staffs 785
Legislative 786
Liaison with the Department of Health and Mental Hygiene 788
Liasion with Third Party Carriers 788
Library and History 791
Long-Term Care and Geriatrics 793
Maryland Medical Journal 794
Med-Chi Insurance Fund 794
Medicine and Religion 795
Medicolegal 795
Nominations 796
Occupational Health 797
Peer Review 797
Physician/Patient Relations 798
Physician Rehabilitation 799
Preventive Medicine and Public Health 800
Professional Ethics 801
Public Relations 801
Reference 802
Scientific Activity 803
Secretary 804
Tel-Med 805
Treasurer 807







At the President's Banquet, outgoing president **George S. Malouf** MD (left) receiving the past-president's medal from **Roland T. Smoot** MD. President elect **J. D. Drinkard** MD is at far right.

Medical and Chirurgical Faculty of the State of Maryland

187th Annual Session—Hunt Valley, Maryland

First Meeting, April 25, 1985 (314th Meeting)
Minutes: House of Delegates

The 314th meeting, first of the 187th Annual Session of the House of Delegates of the Medical and Chirurgical Faculty of the State of Maryland was called to order at 9:36 a.m., President George S. Malouf MD and Secretary Bernard S. Karpers, Jr., MD being present.

The following delegates (or alternates) were registered as being in attendance; an asterisk indicates an alternate delegate:

Allegany County
Victor Felipa
Leslie R. Miles, Jr.
* Clarence J. Vincent

Anne Arundel County
Stephen R. Brown
Allen C. Egloff
Michael J. La Penta
Hilary T. O'Herlihy
Jorge Ramirez

Baltimore City
Raymond M. Atkins
* Aristides C. Alevizatos
Donald M. Barrick
James E. Bell
* Annie M. Bestebreurtje
Paul Bormel
Stephen M. Busky
* Joel M. Cherry
Elliott R. Fishel
Vincent DeP. Fitzpatrick
Marion Friedman
* Sheldon Goldgeier
Stanford M. Goldman
Susan R. Guarnieri
Carlton I. Halle
Michael G. Hayes
John H. Hirschfeld
James H. Hitzrot
* Joseph H. Hooper
* Thomas E. Hunt
* Murray A. Kalish
Misbah Khan
* Jeanne S. Kraus
John B. MacGibbon
Donald W. Mintzer
* Richard S. Munford
Albert Nahum
William F. Renner
Gary L. Rosenberg
Benjamin Rothfeld
Edward L. Suarez-Murias
George Taler
Thomas E. Van Metre, Jr.
Israel H. Weiner

Baltimore County
Andrew A. Alecce
Thomas E. Allen
Sheldon Bearman
John Buckley
Esther Edery
Frank Faraino
A. H. Ghiladi
Gerald A. Glowacki
Christopher M. Harvey
Charles F. Hoesch
Paul G. Koukoulas
John M. Krager
Herbert J. Levickas
Louis J. Pratt, Jr.
William Reichel
Allan G. Scott
Margaret L. Sherrard
John F. Strahan
* J. Carlton Wich

Calvert County
David W. Fricke

Carroll County
Alva S. Baker
Arthur L. Rudo

Charles County
* J. Parran Jarboe
Guillermo E. Sanchez

Dorchester County
Paul A. Stagg

Frederick County
Arthur G. Manalo

Harford County
Rose Mary Bonsack
Philip W. Heuman
Ben E. Oteyza

Howard County
* Frederick G. Bergmann
Thomas F. Herbert
Charles J. Lancelotta

Kent County
Harry P. Ross

Montgomery County
Benjamin Avrunin
Carol L. Bender
* Sharon T. Denny
Lawrence H. Fink
Robert G. Kindred
Charles H. Ligon
Ralph E. Longway
* Jaime F. Marquez
Roger J. Oldham
* Jorge H. Reisin
* Edward J. Richards
Margaret T. Snow
Thomas M. Wilson

Prince George's County
Stanley A. Forster
Andres C. Lara
Reynaldo L. Lee-Llacer
Ricardo Longoria
Joseph J. McDonald
David N. Robb
R. Kennedy Skipton
Elliece Smith
* William A. Warren

Queen Anne's County
John R. Smith, Jr.

Talbot County
Alfred A. Leszczynski

Washington County
Francisco G. Japzon

Wicomico County
Alex Azar
Oswald J. Burton
Thomas C. Hill

Worcester County
Federico G. Arthes
* Francis J. Townsend, Jr.

Council
Manning W. Alden
Ian R. Anderson
Albert M. Antlitz
Ronald R. Cameron
Thomas C. Cimonetti
John B. DeHoff

Benjamin DelCarmen
Donald H. Dembo
Michael R. Dobridge
J. D. Drinkard
James T. Estes
Hubert L. Fiery
Edgar E. Folk, III
Gerald A. Glowacki
John H. Hebb
Bernard S. Karpers, Jr.
Leon E. Kassel
Leon R. Levitsky
Donald T. Lewers
George S. Malouf
J. David Nagel
Hiroshi Nakazawa
Charles F. O'Donnell
Sherman S. Robinson
Donald J. Roop
Marvin Schneider
Aubrey C. Smoot
Roland T. Smoot
Joseph Snyder
Albert J. Strauss
John B. Umhau
Baltasar B. Velez
Henry N. Wagner, Jr.
Karl H. Weaver
Donald W. Wiczer
Kennard L. Yaffe
Jose M. Yosuico

Past Presidents
John R. Davis, Jr.
Francis C. Mayle
Karl F. Mech

Board of Medical Examiners
Arthur T. Keefe, Jr.

Also present were staff personnel.

Invocation

Leslie R. Miles, Jr., Chairman of the Committee on Medicine and Religion, delivered the invocation.

President's Remarks

The President made certain announcements, advising various rules for conduct of House business, as well as providing information on various scientific and social functions scheduled to take place during the session.

Semiannual Minutes

The minutes of the Semiannual Session of the House of Delegates held on Friday, September 14, 1984, in Ocean City, MD, having been distributed to all members and approved by the Executive Committee, were presented to the House for information.

Introduction of Guests

The president introduced the following guests to the House:

Rufus K. Broadaway MD, Member, AMA Board of Trustees, who made a brief speech.

AMA-ERF Checks Presented

Checks in the amount of $17,144 in unrestricted funds, and $4,574 in restricted funds for medical student assistance were presented to Roland T. Smoot MD for the Johns Hopkins University School of Medicine; $26,807 in unrestricted funds, and $4,863 in restricted medical student assistance funds to John M. Dennis MD, Dean of the University of Maryland School of Medicine; and $1,042 in unrestricted funds for the Uniformed Services University of the Health Sciences to Rear Adm. William M. Narva, MC, USN, Vice President of the University.

Other Visiting Guests

The President introduced the following invited guests to those in attendance, each made brief remarks:

Carl Roncaglione MD, President of the West Virginia State Medical Association
Frank Watson MD, President of the Medical Society of New Jersey
Daniel Alvarez MD, President of the Medical Society of Delaware

The efforts of the federal government are not to contain costs, they are to contain payments. This administration has been less than cooperative with the leaders of American medicine to solve these problems. Every physician who cares about the future of American medicine ought to be a member of the American Medical Association. I won't guarantee the AMA will win every fight; but I believe we will eventually win the war for good patient care.

RUFAS K. BROADAWAY **MD, AMA Board of Trustees**
House of Delegates, April 25

Robert Collins MD, President of the Medical Society of the District of Columbia
Harry Kuykendall MD, President of the Medical Society of Virginia

Necrology

Members of the House of Delegates rose in observance of a moment's silence in respect for deceased colleagues as the Secretary read the following necrology:

Allegany County

Donald B. Grove, MD	November 27, 1983
Edwin C. Miller, MD	July 30, 1984

Anne Arundel County

Bruce Cooper Sinclair-Smith MD	January 1, 1985
Francis C. Kirchner MD	April 20, 1984
Charles R. MacDonald MD	May 1, 1984
Theodore G. Osius Jr., MD	November 17, 1984
E. Roderick Shipley MD	September 9, 1984
Ignas Saulynas MD	January 28, 1985
F. X. Paul Tinker MD	March 26, 1985

Baltimore City

Melvin N. Borden MD	May 21, 1984
T. Terry Burger MD	June 9, 1984
Russell S. Fisher MD	May 21, 1984
John Eager Howard MD	February 24, 1985
John T. Howard MD	August 30, 1984
Grace G. Jones MD	October 13, 1984
Samuel Livingston MD	August 22, 1984
David N. Marine MD	December 14, 1984
George McDonald MD	February 24, 1984
Erica F. Moszkowski MD	April 29, 1984
Joseph E. Muse, Jr., MD	July 19, 1984
John A. Myers MD	September 23, 1984
John A. O'Connor MD	October 17, 1984
Arthur J. Owen MD	April 28, 1984
Howard J. Rathbun MD	August 24, 1984
Isadore A. Siegel MD	May 1, 1984
Theodore Stacy MD	July 6, 1984
Leonard Wallenstein MD	February 25, 1985
Aidan E. Walsh MD	March 1, 1985
James E. White MD	February 20, 1985
Walter L. Winkenwerder MD	July 25, 1984
Robert L. Young, Jr., MD	January 11, 1985

Baltimore County

George D. Edwards MD	December 13, 1984
Hossein Golpira MD	June 13, 1984
William H. Kammer, Jr., MD	December 30, 1984
Laurence C. Post MD	December 17, 1984
James A. Lyon, Jr., MD	March 31, 1985

Frederick County

Thomas H. Quill MD	March 27, 1984
Louis R. Schoolman MD	August 3, 1984

Harford County

Paul S. Stonesifer, Jr., MD	September 8, 1984

Howard County

Wesley L. Cashatt MD	October 11, 1984
John F. J. Coolahan MD	October 12, 1984

Montgomery County

Stanley M. Bialek MD	September 25, 1984
Joe M. Blumberg MD	May 19, 1984
Stewart Clapp MD	October 12, 1983
George J. Ellis, Sr., MD	March 10, 1985
Eugene Patrick Flannery MD	May 7, 1984

Prince George's County

George W. Ware MD	March 28, 1985
John M. Warren MD	March 11, 1985

Queen Anne's County

Benjamin D. White MD	April 30, 1984

Talbot County

John T. B. Ambler MD	May 7, 1984
Thurston Harrison MD	January 22, 1985

Washington County

Lloyd A. Hoffman MD	June 19, 1984
Merrill C. Smoot MD	February 25, 1985

Wicomico County

Osborne D. Christenson MD	November 4, 1984

Residents

Anthony A. Arz MD	May 11, 1984

Affiliates

Frank P. Dwyer, Jr. MD	June 8, 1984
Frederick S. Wolf MD	July 30, 1984

Fifty-Year Members

Presentation of Fifty-Year certificates and Pins by the President to the following members took place; awards were mailed to those unable to attend the meeting:

Baltimore City
J. Robert Gibbons MD, Baltimore
Louis P. Hamburger, Jr., MD, Cockeysville
Henry C. Hull MD, Baltimore
Joseph V. Jeppi MD, Baltimore
Henry L. Wollenweber MD, Baltimore

Kent County
Alexander Dick MD, Chestertown

Montgomery County
Read N. Calvert MD, Silver Spring

Emeritus Members

On motion of Donald T. Lewers MD, Council Chairman, the following members were elected to Emeritus Membership in the Faculty, each having received the recommendation of their Component Societies and the Council:

Baltimore City
George W. Borkovic MD, Baltimore
Raymond M. Curtis MD, Baltimore
Walter E. Dandy, Jr., MD, Baltimore
Raymond B. Goldberg MD, Baltimore
Herbert N. Gundersheimer MD, Baltimore
Marjorie H. Hendry MD, Baltimore
T. Brannon Hubbard, Jr., MD, Garrison
John S. Lesinski MD, Baltimore
Lucila P. Lesser MD, Baltimore
Stephen C. Mackowiak MD, Baltimore
Robert E. May MD, Baltimore
John C. Ozazewski MD, Baltimore
J. Emmett Queen MD, Baltimore
C. Lee Randol MD, Baltimore
William B. Rever, Jr., MD, Towson

Baltimore County
Irving R. Beck MD, Baltimore
William T. Dixon MD, Lutherville
Soon Chul Hong MD, Baltimore
Joseph F. LiPira MD, Towson
James N. McCosh MD, Timonium

Carroll County
Julius Chepko MD, Westminster
Harold H. Weinberg MD, Westminster

Frederick County
John M. Culler MD, Frederick

Howard County
Paul R. Ziegler MD, Ellicott City

Montgomery County
Arthur R. Bergman MD, Takoma Park
Claude E. Caylor, Jr., MD, Silver Spring
Delbert R. Dick MD, Langley Park
Irving Feinberg MD, Silver Spring
George A. Gray, Jr., MD, Bethesda
Richard E. Lukes MD, Kensington
Carlos A. Recio MD, Rockville
Webster Sewell MD, Silver Spring
Jonathan M. Williams MD, Silver Spring

Prince George's County
Mary K.L. Sartwell MD, Adelphi
R. Kennedy Skipton MD, Cheverly

Washington County
Paul G.H. Wolber MD, Hagerstown

Worcester County
John M. Buchness MD, Berlin
Dorothy C. Holzworth MD, Snow Hill

Affiliates
Richard B. Hanchett MD, San Pedro, CA
William C. Swatek MD, Senatobia, Miss.

Resolution on Assessment

Dr. Lewers, on behalf of the Council and in accordance with Article III, Section 7 of the Bylaws, offered the following resolution, which was adopted without dissent.

Resolved, That the current $5 assessment of the active membership be increased to $10 per year, effective January 1, 1986, and expiring December 31, 1988;
Resolved, That funds raised from this additional assessment shall be used for the purpose of hiring a part-time Coordinator to supplement the activities of the Committee on Physician Rehabilitation and act as an additional resource for that committee; and be it further
Resolved, That existing accumulated funds for use of the Committee on Physician Rehabilitation be used to fund this part-time Coordinator through January 1, 1986 with details as to employment terms, etc., to be worked out by the Committee, together with the Treasurer.

Resolution on Fee Freeze

Dr. Lewers, on behalf of the Council, moved adoption of the following resolution which, without dissent, was adopted:

Resolved, That the physicians of Maryland be commended for their response to the 1984 House of Delegates' action urging them to freeze their fees for one year;
Resolved, That members of the Medical and Chirurgical Faculty of the State of Maryland continue their pledge to ensure the highest quality of medical care to all Maryland citizens at a cost that is reasonable and appropriate while always remaining vigilant to every opportunity for containment of health care costs, as well as for instances where courtesy and charity can be given in a dignified and appropriate manner; and

Resolved, That Maryland physicians be urged to continue giving special consideration when setting fees for the unemployed, the uninsured and those on Medicare and, when warranted, to accept reduced fees or none at all.

Treasurer's Report

Jose M. Yosuico MD, Treasurer, made a brief report on the 1985 budget as adopted by the Council, which had been distributed to all members prior to the meeting.

Bylaws Committee Report

Reynaldo Lee-Llacer MD, Chairman of the Bylaws Committee, on behalf of the Committee moved adoption of the following bylaw amendment, which was adopted by the required ⅔ vote as follows:

Amend Article XI (Committees) by substituting for Section 13 the following, provided that upon the adoption of this amendment, the present members of the Committee shall determine by lots the classes of membership into which they fall, and the medical staffs represented by members whose terms on the Committee thereby terminate in the current year shall be subject to election in the current year, and the term of the other classes shall terminate one and two years later, respectively:

Hospital Medical Staff Committee

Section 13. *A COMMITTEE ON HOSPITAL MEDICAL STAFFS*, approximately one-third of the members of which shall be chosen for a term of three years, shall annually be elected by the hospital medical staffs of each hospital within the State of Maryland, preferably from among members of the American Medical Association. No such hospital medical staff shall be represented by more than one member. The president of the Faculty may also appoint three members-at-large, and he shall designate the member of the committee who shall serve as chairman. The duties of the committee shall be to provide a direct means of addressing the relationship between members of the Faculty and hospital staffs. The committee shall work with and coordinate activities with the Hospital Medical Staff Section of the American Medical Association.

Council Membership

Dr. Lee-Llacer, on behalf of the Bylaws Committee, moved adoption of the following bylaw amendment which, after debate, was adopted by the required ⅔ vote as follows:

Amend Article VII (Council), Section 1, after the words "immediate past-president" by inserting the words "the deans of medical schools within Maryland."

Meeting Notices

Dr. Lee-Llacer, on behalf of the Bylaws Committee, moved adoption of the following bylaw amendment, which was adopted by the required ⅔ vote as follows:

Amend Article XVI (Amendments), after the words "by a two-thirds vote," by striking out "provided that any amendment which proposes to increase dues or levy an assessment for any class of membership shall be sent to all delegates at least sixty (60) days before the session at which action is to be taken."

A.H. Robins Community Service Award

The President presented the A.H. Robins Community Service Award to Roland T. Smoot MD, Baltimore City.

Photo Contest Winners

The President announced winners of the Photo Contest:
Color Category:
1st place, Erwin Bacmeister, MD, Baltimore
2nd place, Mrs. Patricia Pidlaoan, Glen Burnie
Black-and-White Category:
1st and 2nd place: Laurence Rubin MD, Silver Spring



Roland T. Smoot MD received the 1985 A.H. Robins Award for community service at the Annual Meeting. Soon after he began medical practice, Dr. Smoot sought to increase enrollment of minority students in medicine and the allied health professions. His efforts resulted in large increases in black enrollment both at the University of Maryland Medical School and at the Johns Hopkins University Medical School. But more than increasing enrollment, Dr. Smoot and his wife **Minnie** (left) demonstrated their concern for those students who were often homesick and bewildered. They offered their home, their encouragement, and their solicitude to dozens of students over the years and continue this outreach today. **George S. Malouf** MD congratulates the Smoots.

Nominating Committee Report

Roland T. Smoot MD, Immediate Past-President, on behalf of the Nominating committee, presented the following slate to the House of Delegates:

President-elect
Donald T. Lewers, Easton, Talbot County
(President-elect, 1985–86)
(President, 1986–87)

First Vice President
John B. Umhau, Jr., Chevy Chase, Montgomery County

Second Vice-President
Reynaldo L. Lee-Llacer, Clinton, Prince George's County

Third Vice-President
Leslie R. Miles, Lonaconing, Allegany County

Secretary
Raymond M. Atkins, Baltimore, Baltimore City

Treasurer
Jose M. Yosuico, Laurel, Baltimore City

Committee on Scientific Activity (6-year term)
Jose Martinez, Lutherville, Baltimore County
(1986–1992)

Library and History Committee (5-year term)
Thomas E. Hunt, Baltimore, Baltimore City
(1986–1991)

Finney Fund Committee (5-year term)
John H. Hebb, Baltimore, Baltimore County
(1986–1991)

Board of Medical Examiners (4-year term)
C. Earl Hill, Pasadena, Anne Arundel County
(July 1, 1985–June 30, 1989)
Rose M. Bonsack, Aberdeen, Harford County
(July 1, 1985–June 30, 1989)

Delegates to the AMA
Charles F. O'Donnell, Towson, Baltimore County
(Jan 1, 1986–Dec 31, 1988)
Michael R. Dobridge, Silver Spring, Montgomery County
(Jan 1, 1986–Dec 31, 1988)

Alternate Delegates to the AMA
Joseph Snyder, Silver Spring, Montgomery County
(Jan 1, 1986–Dec 31, 1988)
Hilda I. Houlihan, Salisbury, Wicomico County
(Jan 1, 1986–Dec 31, 1988)

The following nominations were made from the floor for the Board of Medical Examiners:
Ellis Turk MD, Baltimore
Bernard S. Kleiman MD, Towson

The President announced the election of the Board of Medical Examiners will take place immediately following the adjournment of the House of Delegates. He also announced that election of the balance of the slate will take place as the first item of business at the session scheduled for Saturday, April 27, at 2:00 p.m.

The meeting was adjourned at 11:10 a.m. by unanimous consent.

BERNARD S. KARPERS, Jr., MD
Secretary

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BALANCED CALCIUM CHANNEL BLOCKADE!



Low incidence of side effects
CARDIZEM® (diltiazem HCl) produces an incidence of adverse reactions not greater than that reported with placebo therapy, thus contributing to the patient's sense of well-being.

*Cardizem is indicated in the treatment of angina pectoris due to coronary artery spasm and in the management of chronic stable angina (classic effort-associated angina) in patients who cannot tolerate therapy with beta-blockers and/or nitrates or who remain symptomatic despite adequate doses of these agents.

References:
1. Strauss WE, McIntyre KM, Parisi AF, et al: Safety and efficacy of diltiazem hydrochloride for the treatment of stable angina pectoris: Report of a cooperative clinical trial. Am J Cardiol 49:560-566, 1982.
2. Pool PE, Seagren SC, Bonanno JA, et al: The treatment of exercise-inducible chronic stable angina with diltiazem: Effect on treadmill exercise. Chest 78 (July suppl):234-238, 1980.

Reduces angina attack frequency*
42% to 46% decrease reported in multicenter study.[1]

Increases exercise tolerance*
In Bruce exercise test,[2] control patients averaged 8.0 minutes to onset of pain; Cardizem patients averaged 9.8 minutes ($P<.005$).

CARDIZEM®
(diltiazem HCl)

THE BALANCED CALCIUM CHANNEL BLOCKER

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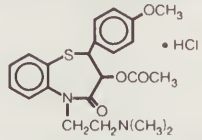
2/84

PROFESSIONAL USE INFORMATION

cardizem®
(diltiazem HCl)
30 mg and 60 mg tablets

DESCRIPTION

CARDIZEM® (diltiazem hydrochloride) is a calcium ion influx inhibitor (slow channel blocker or calcium antagonist). Chemically, diltiazem hydrochloride is 1,5-Benzothiazepin-4(5H)one,3-(acetyloxy) -5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-, monohydrochloride,(+) -cis-. The chemical structure is:



Diltiazem hydrochloride is a white to off-white crystalline powder with a bitter taste. It is soluble in water, methanol, and chloroform. It has a molecular weight of 450.98. Each tablet of CARDIZEM contains either 30 mg or 60 mg diltiazem hydrochloride for oral administration.

CLINICAL PHARMACOLOGY

The therapeutic benefits achieved with CARDIZEM are believed to be related to its ability to inhibit the influx of calcium ions during membrane depolarization of cardiac and vascular smooth muscle.

Mechanisms of Action. Although precise mechanisms of its antianginal actions are still being delineated, CARDIZEM is believed to act in the following ways:

1. Angina Due to Coronary Artery Spasm: CARDIZEM has been shown to be a potent dilator of coronary arteries both epicardial and subendocardial. Spontaneous and ergonovine-induced coronary artery spasm are inhibited by CARDIZEM.
2. Exertional Angina: CARDIZEM has been shown to produce increases in exercise tolerance, probably due to its ability to reduce myocardial oxygen demand. This is accomplished via reductions in heart rate and systemic blood pressure at submaximal and maximal exercise work loads.

In animal models, diltiazem interferes with the slow inward (depolarizing) current in excitable tissue. It causes excitation-contraction uncoupling in various myocardial tissues without changes in the configuration of the action potential. Diltiazem produces relaxation of coronary vascular smooth muscle and dilation of both large and small coronary arteries at drug levels which cause little or no negative inotropic effect. The resultant increases in coronary blood flow (epicardial and subendocardial) occur in ischemic and nonischemic models and are accompanied by dose-dependent decreases in systemic blood pressure and decreases in peripheral resistance.

Hemodynamic and Electrophysiologic Effects. Like other calcium antagonists, diltiazem decreases sinoatrial and atrioventricular conduction in isolated tissues and has a negative inotropic effect in isolated preparations. In the intact animal, prolongation of the AH interval can be seen at higher doses.

In man, diltiazem prevents spontaneous and ergonovine-provoked coronary artery spasm. It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure and, in exercise tolerance studies in patients with ischemic heart disease, reduces the heart rate-blood pressure product for any given work load. Studies to date, primarily in patients with good ventricular function, have not revealed evidence of a negative inotropic effect; cardiac output, ejection fraction, and left ventricular end diastolic pressure have not been affected. There are as yet few data on the interaction of diltiazem and beta-blockers. Resting heart rate is usually unchanged or slightly reduced by diltiazem.

Intravenous diltiazem in doses of 20 mg prolongs AH conduction time and AV node functional and effective refractory periods approximately 20%. In a study involving single oral doses of 300 mg of CARDIZEM in six normal volunteers, the average maximum PR prolongation was 14% with no instances of greater than first-degree AV block. Diltiazem-associated prolongation of the AH interval is not more pronounced in patients with first-degree heart block. In patients with sick sinus syndrome, diltiazem significantly prolongs sinus cycle length (up to 50% in some cases).

Chronic oral administration of CARDIZEM in doses of up to 240 mg/day has resulted in small increases in PR interval, but has not usually produced abnormal prolongation. There were, however, three instances of second-degree AV block and one instance of third-degree AV block in a group of 959 chronically treated patients.

Pharmacokinetics and Metabolism. Diltiazem is absorbed from the tablet formulation to about 80% of a reference capsule and is subject to an extensive first-pass effect, giving an absolute bioavailability (compared to intravenous dosing) of about 40%. CARDIZEM undergoes extensive hepatic metabolism in which 2% to 4% of the unchanged drug appears in the urine. In vitro binding studies show CARDIZEM is 70% to 80% bound to plasma proteins. Competitive ligand binding studies have also shown CARDIZEM binding is not altered by therapeutic concentrations of digoxin, hydrochlorothiazide, phenylbutazone, propranolol, salicylic acid, or warfarin. Single oral doses of 30 to 120 mg of CARDIZEM result in detectable plasma levels within 30 to 60 minutes and peak plasma levels two to three hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3.5 hours. Desacetyl diltiazem is also present in the plasma at levels of 10% to 20% of the parent drug and is 25% to 50% as potent a coronary vasodilator as diltiazem. Therapeutic blood levels of CARDIZEM appear to be in the range of 50 to 200 ng/ml. There is a departure from dose-linearity when single doses above 60 mg are given; a 120-mg dose gave blood levels three times that of the 60-mg dose. There is no information about the effect of renal or hepatic impairment on excretion or metabolism of diltiazem.

INDICATIONS AND USAGE

1. **Angina Pectoris Due to Coronary Artery Spasm.** CARDIZEM is indicated in the treatment of angina pectoris due to coronary artery spasm. CARDIZEM has been shown effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (resting angina with ST-segment elevation occurring during attacks).
2. **Chronic Stable Angina (Classic Effort-Associated Angina).** CARDIZEM is indicated in the management of chronic stable angina. CARDIZEM has been effective in controlled trials in reducing angina frequency and increasing exercise tolerance.

There are no controlled studies of the effectiveness of the concomitant use of diltiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities.

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

1. **Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
2. **Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
3. **Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
4. **Acute Hepatic Injury.** In rare instances, patients receiving CARDIZEM have exhibited reversible acute hepatic injury as evidenced by moderate to extreme elevations of liver enzymes. (See PRECAUTIONS and ADVERSE REACTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS).

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vitro bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outweigh its potential risks in this situation.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences, as well as their frequency of presentation, are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%), AV block (1.1%). In addition, the following events were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrence.

Cardiovascular:	Flushing, arrhythmia, hypotension, bradycardia, palpitations, congestive heart failure, syncope.
Nervous System:	Paresthesia, nervousness, somnolence, tremor, insomnia, hallucinations, and amnesia.
Gastrointestinal:	Constipation, dyspepsia, diarrhea, vomiting, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH.
Dermatologic:	Pruritus, petechiae, urticaria, photosensitivity.
Other:	Polyuria, nocturia.

The following additional experiences have been noted:

A patient with Prinzmetal's angina experiencing episodes of vasospastic angina developed periods of transient asymptomatic asystole approximately five hours after receiving a single 60-mg dose of CARDIZEM.

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: erythema multiforme; leukopenia; and extreme elevations of alkaline phosphatase, SGOT, SGPT, LDH, and CPK. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

OVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with oral diltiazem has been limited. Single oral doses of 300 mg of CARDIZEM have been well tolerated by healthy volunteers. In the event of overdosage or exaggerated response, appropriate supportive measures should be employed in addition to gastric lavage. The following measures may be considered:

Bradycardia	Administer atropine (0.60 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.
High-Degree AV Block	Treat as for bradycardia above. Fixed high-degree AV block should be treated with cardiac pacing.
Cardiac Failure	Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics.
Hypotension	Vasopressors (eg, dopamine or levarterenol bitartrate).

Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating physician.

The oral LD_{50}'s in mice and rats range from 415 to 740 mg/kg and from 560 to 810 mg/kg, respectively. The intravenous LD_{50}'s in these species were 60 and 38 mg/kg, respectively. The oral LD_{50} in dogs is considered to be in excess of 50 mg/kg, while lethality was seen in monkeys at 360 mg/kg. The toxic dose in man is not known, but blood levels in excess of 800 ng/ml have not been associated with toxicity.

DOSAGE AND ADMINISTRATION

Exertional Angina Pectoris Due to Atherosclerotic Coronary Artery Disease or Angina Pectoris at Rest Due to Coronary Artery Spasm. Dosage must be adjusted to each patient's needs. Starting with 30 mg four times daily, before meals and at bedtime, dosage should be increased gradually (given in divided doses three or four times daily) at one- to two-day intervals until optimum response is obtained. Although individual patients may respond to any dosage level, the average optimum dosage range appears to be 180 to 240 mg/day. There are no available data concerning dosage requirements in patients with impaired renal or hepatic function. If the drug must be used in such patients, titration should be carried out with particular caution.

Concomitant Use With Other Antianginal Agents:

1. **Sublingual NTG** may be taken as required to abort acute anginal attacks during CARDIZEM therapy.
2. **Prophylactic Nitrate Therapy**—CARDIZEM may be safely coadministered with short- and long-acting nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.
3. **Beta-blockers.** (See WARNINGS and PRECAUTIONS.)

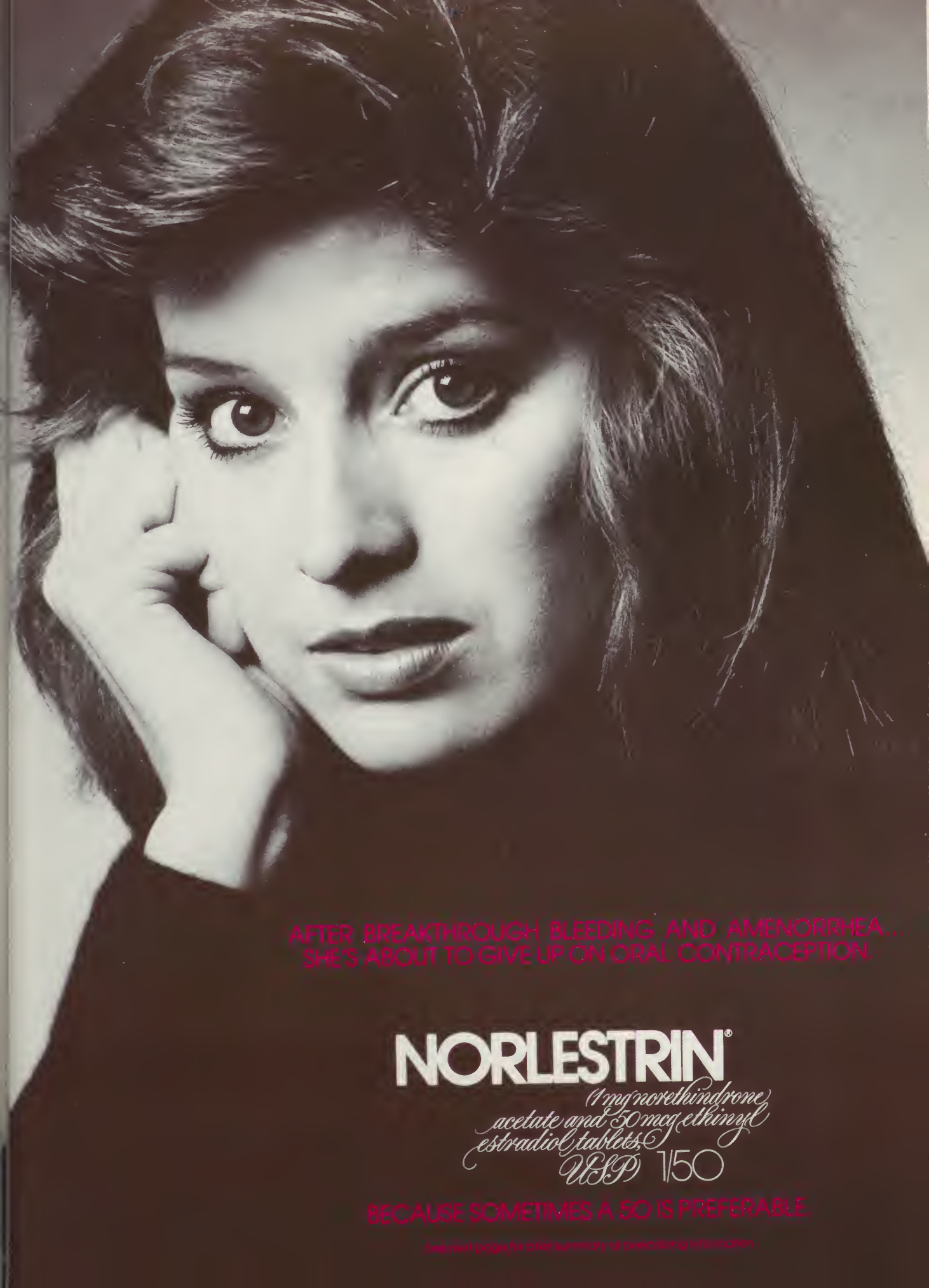
HOW SUPPLIED

Cardizem 30-mg tablets are supplied in bottles of 100 (NDC 0088-1771-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1771-49). Each green tablet is engraved with MARION on one side and 1771 engraved on the other. CARDIZEM 60-mg scored tablets are supplied in bottles of 100 (NDC 0088-1772-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1772-49). Each yellow tablet is engraved with MARION on one side and 1772 on the other.

Issued 4/1/84

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MARION LABORATORIES, INC.
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AFTER BREAKTHROUGH BLEEDING AND AMENORRHEA...
SHE'S ABOUT TO GIVE UP ON ORAL CONTRACEPTION.
NORLESTRIN®
(1 mg norethindrone acetate and 50 mcg ethinyl estradiol tablets, USP) 1/50
BECAUSE SOMETIMES A 50 IS PREFERABLE.
See next page for brief summary of prescribing information.

Brief Summary of Prescribing Information
NORLESTRIN® (norethindrone acetate and ethinyl estradiol tablets, USP)

See section under **Special Notes on Administration and HOW SUPPLIED.**
Before prescribing, please see full prescribing information. A Brief Summary follows.

DESCRIPTION
Norlestrin Products are progestogen-estrogen combinations.

INDICATIONS AND USAGE
Norlestrin Products are indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

In clinical trials with Norlestrin 1/50 involving 25,983 therapy cycles, there was a pregnancy rate of 0.05 per 100 woman-years, in clinical trials with Norlestrin 2.5/50 involving 96,388 cycles, there was a pregnancy rate of 0.22 per 100 woman-years.

Dose-Related Risk of Thromboembolism from Oral Contraceptives: Studies have shown a positive association between the dose of estrogens in oral contraceptives and the risk of thromboembolism. It is prudent and in keeping with good principles of therapeutics to minimize exposure to estrogen. The oral contraceptive prescribed for any given patient should be that product which contains the least amount of estrogen that is compatible with an acceptable pregnancy rate and patient acceptance.

CONTRAINDICATIONS
1. Thrombophlebitis or thromboembolic disorders.
2. A past history of deep-vein thrombophlebitis or thromboembolic disorders.
3. Cerebral vascular or coronary artery disease.
4. Known or suspected carcinoma of the breast.
5. Known or suspected estrogen-dependent neoplasia.
6. Undiagnosed abnormal genital bleeding.
7. Known or suspected pregnancy. (See WARNING No. 5)
8. Benign or malignant liver tumor which developed during the use of oral contraceptives or other estrogen-containing products.

WARNINGS

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

The use of oral contraceptives is associated with increased risk of several serious conditions including thromboembolism, stroke, myocardial infarction, hepatic adenoma, gallbladder disease, and hypertension. Practitioners prescribing oral contraceptives should be familiar with the following information relating to these risks.

1. *Thromboembolic Disorders and Other Vascular Problems.* An increased risk of thromboembolic and thrombotic disease associated with the use of oral contraceptives is well-established. Studies have demonstrated an increased risk of fatal and nonfatal venous thromboembolism and stroke, both hemorrhagic and thrombotic.

Cerebrovascular Disorders: In a collaborative study in women with and without predisposing causes, it was estimated that the risk of hemorrhagic stroke was 2.0 times greater in users than nonusers, and the risk of thrombotic stroke was 4.0 to 9.5 times greater.

Myocardial Infarction: An increased risk of myocardial infarction associated with oral contraceptives has been reported confirming a previously suspected association. These studies found that the greater the number of underlying risk factors (cigarette smoking, hypertension, hypercholesterolemia, obesity, diabetes, history of preeclamptic toxemia) for coronary artery disease, the higher the risk of developing myocardial infarction, regardless of whether the patient was an oral contraceptive user or not. Oral contraceptives, however, were found to be a clear additional risk factor.

It has been estimated that users who do not smoke (smoking is considered a major predisposing condition to myocardial infarction) are about twice as likely to have a fatal myocardial infarction as nonusers who do not smoke. Oral contraceptive users who are smokers have about a fivefold increased risk of fatal infarction compared to users who do not smoke, but about a tenfold to twelvefold increased risk compared to nonusers who do not smoke. The amount of smoking is also an important factor.

Risk of Dose: In an analysis of data, British investigators concluded that the risk of thromboembolism, including coronary thrombosis, is directly related to the dose of estrogen used in oral contraceptives; however, the quantity of estrogen may not be the sole factor involved.

Persistence of Risk: Two studies have suggested that an increased risk may persist for as long as 6 years after discontinuation of oral contraceptive use for cerebrovascular disease and 9 years for myocardial infarction. In addition, a prospective study suggested the persistence of risk for subarachnoid hemorrhage.

Estimate of Excess Mortality from Circulatory Diseases: The risk of diseases of the circulatory system is concentrated in older women, in those with a long duration of use, and in cigarette smokers.

A study of available data from a variety of sources concluded that the mortality associated with all methods of birth control is low and below that associated with childbirth, with the exception of oral contraceptives in women over 40 who smoke.

The risk of thromboembolic and thrombotic diseases associated with oral contraceptives increases with age after approximately age 30 and, for myocardial infarction, is further increased by hypertension, hypercholesterolemia, obesity, diabetes, or history of preeclamptic toxemia, and especially by cigarette smoking.

The physician and the patient should be alert to the earliest manifestations of thromboembolic and thrombotic disorders. Should any occur or be suspected, the drug should be discontinued immediately.

A fourfold to sixfold increased risk of postsurgery thromboembolic complications has been reported in users. If feasible, oral contraceptives should be discontinued at least four weeks before surgery of a type associated with an increased risk of thromboembolism or prolonged immobilization.

2. *Ocular Lesions.* Neuro-ocular lesions, such as optic neuritis or retinal thrombosis, have been associated with the use of oral contraceptives. Discontinue the oral contraceptive if there is unexplained sudden or gradual, partial, or complete loss of vision; onset of proptosis or diplopia; papilledema, or retinal vascular lesions.

3. *Carcinoma.* Long-term continuous administration of estrogen in certain animal species increases the frequency of carcinoma of the breast, cervix, vagina, and liver.

In humans, an increased risk of endometrial carcinoma associated with the prolonged use of exogenous estrogen in postmenopausal women has been reported. However, there is no evidence suggesting increased risk of endometrial cancer in users of conventional combination or progestogen-only oral contraceptives.

Studies found no evidence of increase in breast cancer in women taking oral contraceptives; however, an excess risk in users with documented benign breast disease was reported.

There is no confirmed evidence of an increased risk of cancer associated with oral contraceptives. Close clinical surveillance of users is, nevertheless, essential. In cases of undiagnosed persistent or recurrent abnormal vaginal bleeding, appropriate diagnostic measures should be taken to rule out malignancy. Women with a strong family history of breast cancer, or who have breast nodules, fibrocystic disease, or abnormal mammograms, should be monitored with particular care.

4. *Hepatic Tumors.* Benign hepatic adenomas have been found to be associated with oral contraceptives. Because hepatic adenomas may rupture and may cause death through intra-abdominal hemorrhage, they should be considered in women presenting abdominal pain and tenderness, abdominal mass, or shock.

A few cases of hepatocellular carcinoma have been reported in women taking oral contraceptives. The relationship of these drugs to this type of malignancy is not known at this time.

5. *Usage in or Immediately Preceding Pregnancy: Birth Defects in Offspring, and Malignancy in Female Offspring.* During early pregnancy, female sex hormones may seriously damage the offspring.

An increased risk of congenital anomalies, including heart defects and limb defects, has been reported with the use of oral contraceptives in pregnancy.

There is some evidence that triploidy and possible other types of polyploidy are increased among abortuses from women who become pregnant soon after ceasing oral contraceptives.

Pregnancy should be ruled out before continuing an oral contraceptive in any patient who has missed two consecutive menstrual periods. If the patient has not adhered to the schedule, the possibility of pregnancy should be considered at the time of the first missed period and oral contraceptives should be withheld until pregnancy has been ruled out. If pregnancy is confirmed, the patient should be apprised of the potential risks to the fetus and the advisability of continuation of the pregnancy should be discussed.

Women who discontinue oral contraceptives with the intent of becoming pregnant should use an alternate form of contraception for a period of time before attempting to conceive.

Administration of progestogen only or progestogen-estrogen combinations to induce withdrawal bleeding should not be used as a test of pregnancy.

6. *Gallbladder Disease.* Studies report an increased risk of surgically confirmed gallbladder disease in users of oral contraceptives.

7. *Carbohydrate and Lipid Metabolic Effects.* Because decreased glucose tolerance has been observed in a significant percentage of patients, prediabetic and diabetic patients should be carefully observed while receiving oral contraceptives.

An increase in triglycerides and total phospholipids has been observed.

8. *Elevated Blood Pressure.* An increase in blood pressure has been reported in patients receiving oral contraceptives. The prevalence in users increases with longer exposure. Age is also strongly correlated with development of hypertension. Women who previously have had hypertension during pregnancy may be more likely to develop elevation of blood pressure.

9. *Headache.* Onset or exacerbation of migraine or development of headache of a new pattern which is recurrent, persistent, or severe requires discontinuation of oral contraceptives.

10. *Bleeding Irregularities.* Breakthrough bleeding, spotting, and amenorrhea are frequent reasons for patients discontinuing oral contraceptives. In breakthrough bleeding, nonfunctional causes should be borne in mind. In undiagnosed abnormal bleeding from the vagina, adequate diagnostic measures are indicated to rule out pregnancy or malignancy.

Women with a past history of oligomenorrhea or secondary amenorrhea, or young women without regular cycles should be advised that they may have a tendency to remain anovulatory or to become amenorrheic after discontinuation of oral contraceptives.

11. *Ectopic Pregnancy.* Ectopic as well as intrauterine pregnancy may occur in contraceptive failures.

12. *Breast-Feeding.* Oral contraceptives may interfere with lactation. Furthermore, a small fraction of the hormonal agents in oral contraceptives has been identified in the milk of mothers receiving these drugs.

PRECAUTIONS
1. A complete medical and family history should be taken prior to the initiation of oral contraceptives. The pretreatment and periodic physical examinations should include special reference to blood pressure, breasts, abdomen, and pelvic organs, including Papanicolaou smear and relevant laboratory tests. As a general rule, oral contraceptives should not be prescribed for longer than one year without another examination.
2. Preexisting uterine leiomyomata may increase in size.
3. Patients with a history of psychic depression should be carefully observed and the drug discontinued if depression recurs to a serious degree.
4. Oral contraceptives may cause fluid retention and should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated.
5. Patients with a past history of jaundice during pregnancy have an increased risk of recurrence of jaundice. If jaundice develops, the medication should be discontinued.
6. Steroid hormones may be poorly metabolized and should be administered with caution in patients with impaired liver function.
7. Users may have disturbances in normal tryptophan metabolism, which may result in a relative pyridoxine deficiency.
8. Serum folate levels may be depressed.
9. The pathologist should be advised of oral contraceptive therapy when relevant specimens are submitted.
10. Certain endocrine and liver function tests and blood components may be affected.
(a) Increased sulfobromophthalein retention. (b) Increased prothrombin and factors VII, VIII, IX, and X; decreased antithrombin 3; increased norepinephrine-induced platelet aggregability. (c) Increased thyroid-binding globulin (TBG) leading to increased circulating total thyroid hormone. (d) Decreased pregnanediol excretion. (e) Reduced response to metyrapone test.

Drug Interactions: Reduced efficacy and increased incidence of breakthrough bleeding have been associated with concomitant use of rifampin. A similar association has been suggested with barbiturates, phenylbutazone, phenytoin sodium, tetracycline, and ampicillin.

ADVERSE REACTIONS
An increased risk of the following serious adverse reactions has been associated with oral contraceptives: thrombophlebitis; pulmonary embolism; coronary thrombosis, cerebral thrombosis; cerebral hemorrhage; hypertension; gallbladder disease, benign hepatomas, congenital anomalies.

There is evidence of an association between the following conditions and the use of oral contraceptives, although additional confirmatory studies are needed: mesenteric thrombosis, neuro-ocular lesions, eg, retinal thrombosis and optic neuritis.

The following adverse reactions have been reported in patients receiving oral contraceptives and are believed to be drug related: nausea and/or vomiting, usually the most common adverse reactions, occur in approximately 10% or less of patients during the first cycle. Other reactions, as a general rule, are seen much less frequently or only occasionally: gastrointestinal symptoms; breakthrough bleeding; spotting; change in menstrual flow; dysmenorrhea; amenorrhea during and after treatment; temporary infertility after discontinuance of treatment; edema; chloasma or melasma; breast changes; change in weight; change in cervical erosion and cervical secretion; possible diminution in lactation when given immediately postpartum; cholestatic jaundice; migraine; increase in size of uterine leiomyomata; rash (allergic); mental depression; reduced tolerance to carbohydrates; vaginal candidiasis; change in corneal curvature; intolerance to contact lenses.

The following adverse reactions have been reported and the association has been neither confirmed nor refuted: premenstrual-like syndrome; cataracts; changes in libido; chorea; changes in appetite; cystitis-like syndrome; headache; nervousness; dizziness; hirsutism; loss of scalp hair; erythema multiforme; erythema nodosum; hemorrhagic eruption; vaginitis; porphyria.

Special Notes on Administration
Menstruation usually begins two or three days, but may begin as late as the fourth or fifth day, after discontinuing medication.

After several months on treatment, bleeding may be reduced to a point of virtual absence; reduced flow may be a result of medication and not indicative of pregnancy.

HOW SUPPLIED
Norlestrin 21 1/50 is available in compacts each containing 21 tablets. Each tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

Norlestrin 21 2.5/50 is available in compacts each containing 21 tablets. Each tablet contains 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

Norlestrin Fe 1/50 is available in compacts each containing 21 yellow tablets and 7 brown tablets. Each yellow tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Each brown tablet contains 75 mg of ferrous fumarate, USP. Available in packages of five compacts and packages of five refills.

Norlestrin FE 2.5/50 is available in compacts each containing 21 pink tablets and 7 brown tablets. Each pink tablet contains 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Each brown tablet contains 75 mg of ferrous fumarate, USP. Available in packages of five compacts and packages of five refills.

Norlestrin 28 1/50 is available in compacts each containing 21 yellow tablets and 7 white inert tablets. Each yellow tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

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Second Meeting, April 27, 1985 (315th Meeting)
Minutes: House of Delegates

The 315th meeting, second of the 187th Annual Session of the House of Delegates of the Medical and Chirurgical Faculty of the State of Maryland was called to order at 2:10 p.m., President George S. Malouf MD and Secretary Bernard S. Karpers, Jr., MD, being present.

The following delegates (or alternates) were registered as being in attendance; an asterisk indicates an alternate delegate:

Allegany County
Leslie R. Miles, Jr.

Anne Arundel County
Stephen Brown
* David O'Brien
Raymond P. Srsic

Baltimore City
Donald M. Barrick
James E. Bell
* Joseph I. Berman
Richard Berkowitz
Brian D. Brisco
Stephen M. Busky
Elliott R. Fishel
Vincent DeP. Fitzpatrick
* Emmanuel S. Francois
Marion Friedman
* Robert B. Goldstein
Susan R. Guarnieri
Michael G. Hayes
John H. Hirschfeld
James M. Hitzrot
* Gerald A. Hofkin
* Joseph H. Hooper
* Thomas E. Hunt
Misbah Khan
* Jeanne S. Kraus
John B. MacGibbon
Donald W. Mintzer
John H. Mulholland
* Samuel I. O'Mansky
William F. Renner
Gary L. Rosenberg
Benjamin Rothfeld
* William B. Russell
Edward L. Suarez-Murias
Thomas E. Van Metre, Jr.
Israel H. Weiner

Baltimore County
Thomas Allen
Sheldon Bearman
A. H. Ghiladi
Christopher M. Harvey
Paul G. Koukoulas
John M. Krager
Herbert J. Levickas
Louis J. Pratt, Jr.
William Reichel
Margaret L. Sherrard
* James Andrew Sumner
Margaret Zassenhaus

Carroll County
Arthur L. Rudo

Cecil County
Henry J. Farkas

Dorchester County
Paul A. Stagg

Harford County
Rose Mary Bonsack
Ben E. Oteyza

Montgomery County
DeWitt E. DeLawter
* Sharon T. Denny
Robert G. Kindred
Charles H. Ligon
* Jorge H. Reisin
Roy H. Sandstrom
George W. Schweitzer
Margaret T. Snow

Prince George's County
Lewis H. Dennis
Joseph J. McDonald
R. Kennedy Skipton
Elliece Smith

Talbot County
Alfred A. Leszczynski

Washington County
Francisco G. Japzon

Wicomico County
Alex Azar

Worcester County
Federico G. Arthes

Council
Albert M. Antlitz
Ronald R. Cameron
Thomas C. Cimonetti
Benjamin Del Carmen
Donald H. Dembo
Michael R. Dobridge
J. D. Drinkard
James T. Estes
John H. Hebb
Bernard S. Karpers, Jr.
Leon E. Kassel
Donald T. Lewers
George S. Malouf
Hiroshi Nakazawa
Charles F. O'Donnell
Benjamin S. Pecson
Marvin Schneider
Aubrey C. Smoot
Roland T. Smoot
Joseph Snyder
Albert J. Strauss
John B. Umhau
Baltasar B. Velez
Karl H. Weaver
Kennard L. Yaffe
Jose M. Yosuico

Past Presidents
Richard D. Bauer
Karl F. Mech

Board of Medical Examiners
Arthur T. Keefe, Jr.

Present also were staff personnel.

Board of Medical Examiners Election

The President announced the results of the election of the Board of Medical Examiners that took place on Thursday, April 25, 1985, at Hunt Valley Inn.

Elected to four year terms:
C. Earl Hill MD, Pasadena
Rose M. Bonsack MD, Aberdeen

Faculty Elections

There having been no nominations from the floor and there being only one candidate for each office to be filled, by unanimous consent, the ballot was dispensed with and the following were elected by voice vote:

President-elect
Donald T. Lewers, Easton, Talbot County
(President-elect, 1985–86)
(President, 1986–87)

First Vice President
John B. Umhau, Jr., Chevy Chase, Montgomery County

Second Vice-President
Reynaldo L. Lee-Llacer, Clinton, Prince George's County

Third Vice-President
Leslie R. Miles, Lonaconing, Allegany County

Secretary
Raymond M. Atkins, Baltimore, Baltimore City

Treasurer
Jose M. Yosuico, Laurel, Baltimore City

Committee on Scientific Activity (6-year term)
Jose Martinez, Lutherville, Baltimore County (1986–1992)

Library and History Committee (5-year term)
Thomas E. Hunt, Baltimore, Baltimore City (1986–1991)

Finney Fund Committee (5-year term)
John H. Hebb, Baltimore, Baltimore County (1986–1991)

Delegates to the AMA
Charles F. O'Donnell, Towson, Baltimore County
(Jan 1, 1986–Dec 31, 1988)
Michael R. Dobridge, Silver Spring, Montgomery County
(Jan 1, 1986–Dec 31, 1988)

Alternate Delegates to the AMA
Joseph Snyder, Silver Spring, Montgomery County
(Jan 1, 1986–Dec 31, 1988)
Hilda I. Houlihan, Salisbury, Wicomico County
(Jan 1, 1986–Dec 31, 1988)

MMPAC Report

Mrs. Helen Boyer, Chairman of the Maryland Medical Political Action Committee, made a report to the House of Delegates, which will be published in the annual reports.

Auxiliary Report

Mrs. Mildred Taylor, Auxiliary President, made a report to the House of Delegates, which will be published in the annual reports.

Reference Committee Report

Aubrey C. Smoot MD, Chairman of the Reference Committee, on behalf of the Committee, reported Resolution 1A/85 and moved adoption of a substitute resolution which, in turn, was amended by a substitute offered by Donald M. Barrick MD. The latter, as modified by unanimous consent replaced the Committee substitute and was then adopted as the text of Resolution 1A/85 as follows:

Substitute Resolution 1A/85 Adopted

Whereas, The federal government enacted legislation to create Professional Review Organizations as a cost containment measure;
Whereas, the federal government devised objectives that a prospective professional review organization was obligated to devise criteria to meet;
Whereas, The Medical and Chirurgical Faculty reactivated the Maryland Foundation for Health Care for the purpose of securing the professional review organization contract for Maryland;
Whereas, The Maryland Foundation for Health Care devised criteria in accordance with the objectives stated by the federal government in order to obtain the professional review organization contract;
Whereas, The Maryland Foundation for Health Care was successful in obtaining the professional review organization contract for Maryland; and
Whereas, The physicians of Maryland have raised serious doubts about the quality of care dictated by these criteria as they relate to the admission of patients to hospitals; therefore, be it
Resolved, That the Medical and Chirurgical Faculty of Maryland strongly recommends to the Maryland Foundation for Health Care that it restudy criteria established in the professional review organization contract, in association with the specialty societies of Maryland, within the next 90 days and revise any and all criteria found to have a potentially

adverse effect on the quality of medical care rendered patients in Maryland.

Substitute Resolution 2A/85 Adopted

Dr. Smoot, on behalf of the Reference Committee reported Resolution 2A/85 and moved adoption of a substitute resolution. After debate, the previous question was ordered, and Resolution 2A/85, as amended, was adopted as follows:

Whereas, During the past several months, a committee of the Baltimore City Medical Society has examined the public's perception of the physicians and found that the public has a negative perception of the profession;

Whereas, While this negative perception has been generated partly by unfavorable media reports, it has been learned that physicians may be unwittingly furthering this negative perception in their relationships with their patients by exhibiting behavior that is not consonant with the profession's own standards of excellence;

Whereas, This negative public perception has an adverse effect on the Faculty's ability to achieve some of its purposes as stated in the preamble of the bylaws, i.e.

"... secure the enactment of just laws relating to the practice of medicine and the public health ... and to enlighten and direct public opinion so that the profession shall become more useful in the prevention of disease, in prolonging and adding comfort to life and in promoting a satisfactory distribution of medical care to the citizens of Maryland."

therefore, be it

Resolved, That a major activity of the Faculty is to promote a positive relationship between the patient and the physician and to that end, be it further

Resolved, That the Public Relations Committee be instructed to develop and direct an effort toward improving and maintaining positive relationships between individual patients and their physicians and to coordinate the activities of local medical societies in this endeavor.

The President advised there would be a meeting of the new Council immediately following adjournment of the House of Delegates.

He presented the gavel to the incoming President, J. D. Drinkard MD, who made brief comments.

The President expressed his appreciation to the House for the privilege of serving as President and then declared the meeting adjourned sine die, at 3:15 p.m.

BERNARD S. KARPERS, JR., MD
Secretary

Medicolegal Hotline

for any emergency

August	Jeannette Plante, Esq.	301-752-1630
	Arthur Kaufman MD	301-341-4984
September	Patti Zimmerman, Esq.	301-727-1164
	Israel H. Weiner MD	301-825-2600

Annual Reports of Committees

Ad Hoc Building

Mr. President and Members of the House of Delegates:

During the past year, the Faculty has seen come to fruition the long-awaited plans for expansion of our headquarters building. By this time next year, dedication ceremonies for this expanded facility will have been held.

Contracts have been let for the construction and renovation activities; funds are in hand for the majority of the costs, and a fund-raising drive is under way to raise the remainder.

Plans are being made for a class reunion of all graduates of the former School #49.

The net worth of the Faculty will be increased substantially when all this activity is completed.

GEORGE S. MALOUF **MD, Chairman, Hyattsville**
CHARLES R. CHANEY **MD, Hagerstown**
RONALD R. CAMERON **MD, Rockville**
BERNARD S. KLEIMAN **MD, Baltimore**
REYNALDO L. LEE-LLACER **MD, Clinton**
P. GREGG RHODES **MD, Easton**
JANE O. SEELY **MD, Annapolis**

Alcoholism

Mr. President and Members of the House of Delegates:

At the close of the 1985 Annual Meeting, the Committee on Alcoholism completed its seventh year as a full, standing committee of the Faculty. The committee held monthly meetings throughout the year with one major goal in mind: to educate the medical profession and the public with respect to alcoholism as a disease.

The committee continues to maintain a broad membership by drawing on the expertise of physicians as well as representatives from the Department of Health and Mental Hygiene, the Baltimore City Health Department, the American Council on Alcoholism, clergy, and from major industrial companies throughout Maryland.

The committee's major focus this past year was the development of an educational training program to be presented to the medical staffs as well as administrative staffs of hospitals in Maryland. The committee held meetings with the Alcoholism Control Administration as well as the Maryland Hospital Association in order to develop the most effective way of presenting this educational program. The aim is to educate both the medical staff and the administrative staff as to how the treatment of alcoholic patients can greatly benefit the patient, the community, and the hospital. It is hoped the committee will continue to work on this important project.

The committee also participated in the 1985 Annual Meeting of the Faculty by cosponsoring a well-received session with the Faculty's Committee on Physician Rehabilitation. Kenneth Williams MD, from Pennsylvania, was the main speaker of the session and John H. Hirschfeld MD, Co-Chairman of the Committee, was the moderator. Dr. Williams spoke on "What the Physician Should Know About Alcoholism." He related his experiences with alcoholic patients and various ways of recognizing problems.

The committee also sponsored a Lunch-and-Learn Session with Michael Potash MD, a member of this committee as the speaker. Dr. Potash entertained a full table of guests who were most enthused by his talk, "Use of Drugs in Alcoholic Patients."

This committee continues to monitor the many areas of educating residents of Maryland with regard to this deadly disease and is eager and willing to continue its course.

The Co-Chairmen appreciate the time devoted by members of this committee to this important aspect of Faculty activity.

JOHN H. HIRSCHFELD **MD, Co-Chairman**
ABRAHAM M. SCHNEIDMUHL **MD, Co-Chairman**
CONRAD B. ACTON **MD**
FEDERICO G. ARTHES **MD**
MIRZA H. A. BAIG **MD**
RICHARD CHASEN **MD**
CHARLOTTE COATES-WILKES **MD**
MITHAT CORUH **MD**
WILLIAM T. DIXON **MD**
SUDHIR K. DUTTA **MD**
CLAUDE R. FEINSTEIN **MD**
W. RICHARD FERGUSON **MD**
SURYABALA GOSWAMI **MD**
PAUL F. GUERIN **MD**
ARTHUR M. HILDRETH **MD**
ROBERT R. KENT **MD**
HARRY F. KLINEFELTER **MD**
S. EUGENE LONG **MD**
SIDNEY J. MALAWER **MD**
GEORGE G. MERRILL, JR., **MD**
MICHAEL D. POTASH **MD**
ALIX C. REY **MD**
BRUCE T. TAYLOR **MD**
MAXWELL N. WEISMAN **MD**
CHARLES WHITFIELD **MD**

Advisory Members
RONALD N. FLAMER
SANDRA K. HILL
ISADORE KAPLAN **MD**
LUDWIG L. LANKFORD
MARC B. LIPTON **PHD**
PHIL McKENNA
ROBERT MILLER
SEANA SHAW **MD**
REVEREND HARRY SHELLEY
EMMA J. STOKES **PHD**

American Medical Association Education and Research Foundation

Mr. President and Members of the House of Delegates:

The financial support provided by Med-Chi members is vitally important to the cause of our area medical schools and the Medical Student Assistance Fund. In this era of change at all levels, continued assistance by the Medical Family remains the major source of unrestricted aid to the medical schools, now that federal and state funding has been reduced to an unrealistic low. It is a sincere hope that the challenge of our medical schools' plight will inspire Faculty members to increase their support.

Faculty Contributions
June 1, 1984–May 31, 1985

Counties	
Allegany	$ 450
Anne Arundel	1,245
Baltimore City	4,155
Baltimore	2,580
Calvert	105
Caroline	---
Carroll	210
Cecil	210
Charles	195
Dorchester	105
Frederick	240
Garrett	75
Harford	690
Howard	525
Kent	60
Montgomery	4,005
Prince George's	2,250
Queen Anne's	30
Somerset	---
St. Mary's	45
Talbot	375
Washington	555
Wicomico	840
Worcester	45
Total	$18,435
Maryland Physicians' Direct Contributions to National—June 1, 1984–March 31, 1985	$6,529

ELIZABETH A. LINHARDT, **State Chairman AMA-ERF**

Auxiliary

Mr. President and Members of the House of Delegates:

"Communication" has been the Auxiliary theme for 1984–1985, and at our Annual Convention we gave information on Maryland's activities to our Eastern Regional delegates, friends from Southern Medical Association Auxiliary, and to National Representatives from Utah and California. We could tell them that this year our state and county groups participated in over 40 health projects covering pre- and post-natal care, adolescent pregnancy, juvenile diabetes, mental retardation, child abuse, care of the aging, and daily good health habits. These projects have been reported in newspapers, the *Journal*, our *Hygeia Filiae*, radio and television. Our Maryland Auxiliary is becoming known for its hard work and dedication.

On the Legislative front we have been participating in The Healthy Majority's stand against smoking, continued our write-in campaign for car seats, seat belts, and drunk-driving laws. We have joined the Medical and Chirurgical Faculty's Legislative Committee to learn more about Maryland's legislation that affects the medical world. MMPAC was chaired by an auxilian, Mrs. M. McKendree Boyer, and we sent members to learn about and work with the PAC program.

Such long-term activities have helped our members to find their goals. Thanks to tireless efforts of Members-at-Large Chairman, Madrian Snyder, and to county representatives, the Frederick members-at-large decided on April 22, 1985 to reform. They will be installed in September as our 13th component auxiliary. This decision tells how meaningful our organization can be to physician spouses and of its worth to community and state.

Our auxiliary programs grow out of community and national needs implemented at each level according to expertise and requirements. An outline describing the Auxiliary, its purpose, and focus was recently prepared for the AMA Board of Trustees. This outline states "The American Medical Association Auxiliary is a nationwide network of physician spouses with a common bond—and a common goal—to improve health and quality of life for people in their communities. As the volunteer arm of the AMA, the Auxiliary seeks to extend the goals of the medical profession into the community through:

- Supporting medical education by raising funds for AMA-ERF:
- Legislative action to insure sound health legislation;
- Health projects to improve the quality of life of others."

In addition to community efforts we also focus on the

problems of change in medicine; on medical malpractice—an AMA Auxiliary booklet is coming out this Fall; education and support groups for the impaired physician, spouse and family; and emphasis on physician image to reinforce the value of physicians and medicine today.

We have worked particularly hard to communicate our spouses' dedication to the best in medicine for their patients. Our message says "Your Doctor Cares" via the doctor's spouse who cares. Good health and good health care are important to us all, and your auxiliary says to all who hear, "we care."

MILDRED S. TAYLOR, **President**

Bylaws

Mr. President and Members of the House of Delegates

The Bylaws Committee submits the following bylaw changes for consideration of the House of Delegates:

1. Amend Article XI (Committees) by substituting for Section 13 the following, provided that upon the adoption of this amendment, the present members of the Committee shall determine by lots the classes of membership into which they shall fall, and the medical staffs represented by members whose terms on the Committee thereby terminate in the current year shall be subject to election in the current year, and the term of the other classes shall terminate one and two years later, respectively:

> Section 13. *A COMMITTEE ON HOSPITAL MEDICAL STAFFS*, approximately one-third of the members of which shall be chosen for a term of three years, shall annually be elected by the hospital medical staffs of each hospital within the State of Maryland, preferably from among members of the American Medical Association. No such hospital medical staff shall be represented by more than one member. The president of the Faculty may also appoint three members-at-large, and he shall designate the member of the committee who shall serve as chairman. The duties of the committee shall be to provide a direct means of addressing the relationship between members of the Faculty and hospital staffs. The committee shall work with and coordinate activities with the Hospital Medical Staff Section of the American Medical Association.

This change is being proposed at the request of the Committee on Hospital Medical Staffs. It is similar in some respects to the proposal defeated at the House of Delegates session on Friday, September 14, 1984.

The Bylaws Committee recommends this change be adopted.

2. Amend Article VII (Council), Section 1, after the words "immediate past-president" by inserting the words "the deans of medical schools within Maryland."

This change is proposed by the Council. It is believed the deans of all three medical schools in Maryland would add considerably to the deliberations of the Council.

The Bylaws Committee recommends this amendment be adopted.

3. Amend Article XVI (Amendments), after the words "by a two-thirds vote," by striking out "provided that any amendment which proposes to increase dues or levy an assessment for any class of membership shall be sent to all delegates at least sixty (60) days before the session at which action is to be taken."

This change would enable a more orderly progression of notices to House of Delegates' members in those years when an assessment or dues change may be proposed. The bylaws provide the call to the session be sent 30 days before the House meets. The present requirement necessitates two mailings to all members, with the concurrent additional expenses of mailing, etc.

The Bylaws Committee recommends adoption of this amendment.

The Bylaws Committee considered other items of business but has no recommendations at this time.

REYNALDO L. LEE-LLACER **MD, Chairman, Hyattsville**
MICHAEL A. BOLOGNESE **MD, Gaithersburg**
CHARLES F. O'DONNELL **MD, Towson**
STEVEN C. SANDLER **MD, Landover**

Continuing Medical Education Review

Mr. President and Members of the House of Delegates:

The Continuing Medical Education Review Committee held five meetings during the past year. Action was taken on the following organizations that are accredited by Med-Chi:

† 1. American Cancer Society–Maryland Division
2. American Heart Association–Maryland Affiliate
3. American Lung Association of Maryland
† 4. Anne Arundel General Hospital
5. Baltimore County General Hospital
† 6. Bon Secours Hospital
7. Calvert Memorial Hospital
8. Carroll County General Hospital
† 9. Center for Health Education, Inc.
10. Chestnut Lodge
†11. Children's Hospital, Inc.
12. Church Hospital Corporation
13. Community Psychiatric Clinic, Inc.

14. Crownsville Hospital Center
15. Doctor's Hospital of Prince George's County
†16. Dorchester General Hospital
17. Edward W. McCready Memorial Hospital, Inc.
18. Fallston General Hospital
19. Franklin Square Hospital
20. Frederick Memorial Hospital
†21. Good Samaritan Hospital
22. Greater Baltimore Medical Center
23. Greater Laurel Beltsville Hospital
24. Harford Memorial Hospital
25. Holy Cross Hospital
26. Howard County General Hospital, Inc.
27. Kernan Hospital
28. Levindale Hebrew Geriatric Center & Hospital, Inc.
†29. Lutheran Hospital
30. Maryland General Hospital
31. Maryland Hospital Education Institute
†32. Maryland Psychiatric Society
33. Maryland Radiological Society
34. Memorial Hospital–Cumberland
35. Memorial Hospital of Easton, Maryland
36. Mercy Hospital
37. Montgomery County Medical Society
38. Montgomery General Hospital
39. Montgomery Village Seminars
40. The Neurology Center, P.A.
41. North Arundel Hospital
42. North Charles General Hospital
43. Obstetrical & Gynecologic Society of Maryland
44. Peninsula General Hospital
45. Prince George's County Medical Society
46. Prince George's General Hospital
†47. Provident Hospital
48. Sacred Heart Hospital
49. Saint Agnes Hospital
50. Saint Joseph Hospital
*51. Shady Grove Adventist Hospital
†52. Sheppard & Enoch Pratt Hospital
53. Sinai Hospital
54. South Baltimore General Hospital
55. Southern Maryland Hospital, Inc.
56. Spring Grove Hospital
57. Springfield Hospital Center
58. Suburban Hospital
†59. Taylor Manor Hospital
60. Union Memorial Hospital
61. University Health Center, University of Maryland
62. Veterans Administration Hospital–Perry Point
63. Washington Adventist Hospital
64. Washington County Hospital

Note: *—indicates accreditation was granted during 1984–1985
† —indicates accreditation was renewed during 1984–1985
Those hospitals/organizations having no marking were granted accreditation in previous years.

The committee's Third Annual Meeting of Directors of Continuing Medical Education was held on April 26, 1985 and was well received by the attendees. The committee is considering holding two workshops next year for all Directors of intrastate accredited organizations in Maryland.

The accreditation Council for Continuing Medical Education, which is the national accrediting body for Category I CME activities, approved Guidelines for Commercial Support of CME and its amended Statement on National vs. Intra-State Accreditation.

I would like to thank each member of the committee for his/her active involvement in the activities of the committee.

***JONATHAN M. SUTTON* MD, Chairman**
***IAN ANDERSON* MD**
***JONATHAN D. BOOK* MD**
***IRVIN H. COHEN* MD**
***WORTH B. DANIELS* MD**
***JOHN M. DENNIS* MD**
***SALVATORE DONOHUE* MD**
***KEVIN N. HENNESSEY* MD**
***JOHN C. HYLE* MD**
***CAROL J. JOHNS* MD**
***SAAD A. KASSEM* MD**
***HENRY H. KWAH* MD**
***EUGENE P. LIBRE* MD**
***GEORGE L. MORNINGSTAR* MD**
***ABDUL NAYEEM* MD**
***MARCOS J. PUPKIN* MD**
***IBRAHIM A. RAZZAK* MD**
***R. KENNEDY SKIPTON* MD**
***EDWIN H. STEWART, JR.*, MD**
***EDWIN WITKIN* MD**
***JOHN W. BULLARD* PHD (Advisory)**
***JACK L. MASON* PHD (Advisory)**

Council

Mr. President and Members of the House of Delegates:

Regular Council meetings were held during the year along with Executive Committee sessions. Many major issues were discussed: most have been reported to the House of Delegates. Items of more than routine concern on which action was taken by the Council included the following:

A total revision of the Compendium of Laws, Regulations, Opinions and Policies was completed. The Attorney-General has issued a business-review letter that states the enforcement intentions of the Attorney-Gen-

eral and finds the revision consistent with antitrust law.

A comprehensive Public Relations program has been developed and instituted. This will be expanded following adoption of the resolution urging a more proactive approach by the House of Delegates.

The question of a "dual" fee schedule was also resolved with the Commission on Medical Discipline.

An expansion of services by the Committee on Physician Rehabilitation was approved by employment of a part-time counselor.

A formal retreat for Faculty leadership will be held on an annual basis.

The Department of Health and Mental Hygiene issued a directive that all physicians performing laboratory tests in their offices must participate in a proficiency testing program. After negotiation with the department, this directive was substantially amended to delete from this ruling simple items such as urinalysis and other routine tests. The specialty societies have been requested to provide opinions on whether additional in-house laboratory tests should be exempted.

It has been a pleasure to serve as Council Chairman for the past year. Accomplishments of objectives would not be possible without the cooperation of the individual membership.

DONALD T. LEWERS MD
Council Chairman

Curator

Mr. President and Members of the House of Delegates

During this past year, a water-color portrait of the Faculty Building prepared by the architects of the building in 1908 to illustrate the proposed facade was sent to a conservator at the Johns Hopkins University to be restored. The Faculty's drawing of the original Maryland Hospital is currently being similarly restored.

Also during this past year, the gold leaf frame for one of the Faculty's large portraits was destroyed by water leaking from the Osler Hall roof during a particularly violent rainstorm. The damage was covered under the Faculty's fine arts policy.

E. DAVID WEINBERG MD

Delegates to the AMA House of Delegates

Mr. President and Members of the House of Delegates:

Your delegation to the AMA House of Delegates attended the Interim Meeting in Hawaii from December 2 through December 5, 1984. All sessions of the House were covered, and the Delegation met in various caucuses to discuss issues being voted on at House meetings. Delegates, Alternates, and staff attended the Reference Committee hearings to listen to the discussion that took place on various proposals up for consideration of the AMA House. A summary of the actions taken at this Interim AMA House session follows.

Boxing

The House considered four resolutions calling for opposition to the sport of boxing. The House combined these resolutions into a clear statement that places the Association in the forefront of organizations calling for a total ban on boxing. This issue received much national media attention.

The House called on the AMA to:

- Encourage the elimination of both amateur and professional boxing, a sport in which the primary objective is to inflict injury.
- Communicate its opposition to boxing to appropriate regulating bodies.
- Assist state medical societies to work with their state legislatures to enact laws to eliminate boxing in their jurisdictions.
- Educate the American public, especially children and young adults, about the dangerous effects of boxing on the health of participants.

Chelation Therapy (CSA Report F, Resolution 66)

Another timely issue involves use of chelation therapy. The House spent much time in developing a policy statement on this controversial treatment. The policy reads:

RESOLVED, AMA reports show there is no scientific documentation that the use of chelation therapy is effective in the treatment of cardiovascular disease, atherosclerosis, rheumatoid arthritis, and cancer; and be it further

RESOLVED, That if chelation therapy is to be considered a useful medical treatment for anything other than heavy metal poisoning, hypercalcemia, or digitalis toxicity, it is the responsibility of its proponents to (a) conduct properly controlled scientific studies, (b) adhere to FDA guidelines for the investigation of drugs, and (c) disseminate results of scientific studies in the usually accepted channels.

Professional Liability (B/T Reports K and BB)

The House approved two progress reports on the Association's activities in professional liability.

One report presents the results of the AMA's Committee on Professional Liability's study of costs, tort reform, and other aspects of this complex problem. The committee was established in 1982.

Another reports on the activities of the Special Task Force on Professional Liability established by the Executive Vice President last June. The Task Force's purpose is to coordinate, set priorities, and expand the AMA's activities in the professional liability area.

Public Image of Physicians (B/T Report OO, Resolutions 2 and 30)

Concern for negative public opinion toward physicians was uppermost in the minds of the delegates. The House approved a comprehensive and thoughtful report on the Association's current activities and plans for improving the public image of physicians. The report noted:

- Organizational efforts to improve the public image of physicians are inherently limited and can never replace the actions of individual physicians committing themselves to spending more time with patients, giving them better instructions, and discussing their fees.
- Public perceptions take many years to form, and since the problem has been developed over a long time, it will not be solved quickly.

  Public perceptions of physicians are often inconsistent, and at times contradictory depending upon the background and experience of the individual.

  Public expectations, another image issue, are often unattainable.

In addition to the above report, the House adopted a substitute resolution formulated by the Reference Committee. It called upon the AMA to:

- Strengthen its efforts to increase the public's awareness that physicians are patient advocates.
- Develop and implement an immediate program to focus on increasing the public's understanding of key changes occurring in health care delivery and the impact such changes will have on health care quality and access.
- Plan a long-range national public education campaign utilizing consultants with established reputations.
- Provide assistance and encouragement to state and county associations to develop and implement similar public awareness programs and monitor and evaluate such programs for their effectiveness.

Benefits of Unified Membership (B/T Report DD)

The House approved several recommendations of the Board of Trustees providing additional benefits to members in unified states. The new benefits are designed to encourage and retain unification. Currently only Oklahoma and Illinois are unified states.

The new benefits include:

- Services of an AMA ombudsman within the organizational structure.
- Ten percent dues discount for members excluding students and residents.
- Staff services for special projects.
- Special briefings for officers of unified societies.
- A special Advisory Committee to meet regularly with the Executive Committee of the Board of Trustees and the AMA's Executive Vice-President.
- A higher reimbursement rate to constituent societies for dues collection.

Also, the House asked the Board of Trustees to study alternative mechanisms to provide membership incentives for all state, county, and specialty societies who have successful recruitment programs.

AMA Budget

The House approved a Fiscal Year 1985 budget based on operating revenues of $126,430,000 and operating expenses of $124,580,000 with an anticipated favorable balance of $1,850,000. Incorporating an AMACO gain of $670,000 and a provision for income taxes of $930,000, the anticipated revenue in excess of expense is $1,590,000.

There is no dues increase for 1985.

Before the House considered the budget, the Reference Committee cautioned the delegates that the $1.6-million is a narrow margin and about 1 percent of the total budget. It imposes severe limitations on the growth of activities that can occur in the year ahead without additional revenues or displacement of existing activities.

Peer Review Organizations (Resolutions 10, 19, 39, 43, 49)

The House considered six resolutions regarding various aspects of HCFA's implementation of PRO. Several speakers emphasized the difficulties of negotiating realistic performance objectives in the PRO contracts. Also, delegates complained about the inappropriate emphasis on cost constraint rather than the quality of services provided.

The House directed the AMA to:

- Continue its support for professionally directed programs of medical peer review that place emphasis on quality rather than cost.

- Actively oppose HCFA's use of arbitrary admission and quality objectives in the activities of PRO.
- Implement a PRO monitoring system to obtain documentation necessary to redress PRO implementation problems through legislative and regulatory means.
- Urge the Federation to collect and provide information to the Association.
- Actively seek legislation to correct demonstrated inequities in the implementation of the PRO program.

Opinions of the Judicial Council (JC Reports A, B, C, D)

The House discussed and approved five ethical issues in considering four important reports from the Judicial Council.

1. "Physician-Patient Relationship: Respect for Law and Human Rights," which prohibits illegal discrimination in the physician-patient relationship.
2. "Terminal Illness—Patients Preferences," which relates to "living wills" authorizing withdrawal from life support systems when the patient is irreversibly terminally ill.
3. "New Medical Procedures," which states that physicians have an obligation to share their knowledge and skills, and to report the results of their research.
4. "Surrogate Parenting," which urges couples with infertility problems to investigate the alternatives available to them, including adoption. The Judicial Council believes that surrogate motherhood presents many ethical, legal, psychological, societal, and financial concerns and does *not* represent a satisfactory reproductive alternative for people who wish to become parents.
5. "Hospital-Physician Risk-Sharing Arrangements under DRGs," which advises that physicians may not derive a profit, nor be financially penalized, nor risk loss of hospital privileges under profit-or-loss-sharing agreements.

Hospital Medical Staff Section

With increasing maturity and sophistication, the Hospital Medical Staff Section continues to grow in influence within the House of Delegates. The HMSS at its fourth assembly meeting grappled with the problems of physician-hospital relations.

Over 400 representatives attended and submitted 14 resolutions to the AMA House. Virtually every state and territory was represented and the delegates learned that 31 state medical associations have created similar sections to deal with these issues at the local level.

Medical Acts by Unlicensed Individuals (Resolutions 21, 41, 68, 96)

The encroachment of nonphysicians into the practice of medicine stimulated four resolutions and much debate in the House.

Although AMA policy on the issue was reaffirmed, the delegates called for more aggressive actions, including:

- Monitoring legislative and regulatory activities.
- Disseminating information concerning such activity as expeditiously as possible.
- Developing a proactive program to provide AMA legislative and staff support to assist state medical and specialty societies in their efforts to oppose enactment of new legislation that authorizes independent practice of medicine by individuals who are not licensed to practice medicine and surgery in all its branches.

Scientific Reports

The House agreed to permit the publication of reports from the Council on Scientific Affairs without approval of the House. This new practice will allow earlier dissemination of scientific information.

At this meeting the Council submitted a number of scientific reports. Topics included:

- The Health Effects of Agent Orange
- Diagnostic and Treatment Guidelines for Child Abuse and Neglect
- Effects of Toxic Chemicals on the Reproductive Cycle
- Nicotine Chewing Gum for Cessation of Smoking
- Guidelines for Reporting Estimate of Probability of Paternity

AMPAC Year-End Report

The American Medical Political Action Committee (AMPAC) enjoyed a record-breaking year in 1984, AMPAC Chairman Fred J. Rainey MD told the AMA House of Delegates.

During the 1983–84 election cycle, Dr. Rainey said, AMPAC participated in 578 campaigns, with a 90 percent success rate. He noted this included support for 233 Democrats and 345 Republicans, proving the bipartisan nature of the organization and demonstrating that "party labels have no place in our decisions."

Dr. Rainey also said AMPAC membership now stands at a record 55,500, and the organization had raised $3.7-million in campaign funds in 1983–84, up from $2.4-million in the previous election cycle.

Conclusion

AMA House meetings provide a unique educational

opportunity, and we would encourage you to attend and participate. Any member of the Association may present testimony at the Reference Committee hearings and, of course, corridor discussions on the issues provide ample opportunities to get your views across.

If you can't come to the meeting you can be represented through your delegate. Let your delegation know your opinions. You also can prepare a resolution and request that it be submitted to the House.

Many AMA policies began with an individual physician who had a good idea and coaxed it through the democratic process.

Delegates:
CHARLES F. O'DONNELL **MD, Chairman, Baltimore**
ALBERT M. ANTLITZ **MD, Cochairman, Baltimore**
MANNING W. ALDEN **MD, Annapolis**
DONALD T. LEWERS **MD, Easton**
GEORGE S. MALOUF **MD, Hyattsville (also President)**
ROLAND T. SMOOT **MD, Baltimore**

Alternates:
IRVING A. COHEN **MD, Baltimore (Resident)**
MICHAEL R. DOBRIDGE **MD, Silver Spring**
J. ROY GUYTHER **MD, Mechanicsville**
JOHN H. HEBB **MD , Towson**
JEFFREY H. HELLMAN, **Baltimore (Student)**
HENRY N. WAGNER **MD, Baltimore**

Drugs

Mr. President and Members of the House of Delegates:

The committee met only once during the past year, simply because there was no business to be transacted. The cases referred to the chairman, as Consultant to the Division of Drug Control, were not considered serious enough to require committee decisions. It has been surprising and, in a sense, gratifying to note that referrals of questionable prescribing by Maryland physicians have been so notably reduced.

The Governor set up a Commission on Prescription Drugs, which made several suggestions. This brought about discussion and suggestion from a legislator that another Commission be set up, including representatives of the medical and pharmacy professions and other groups, to develop methodology for dealing with prescription drug abuse. As a result of the work accomplished by the Governor's Commission, Med-Chi initiated a study of the feasibility of conducting an AMA-sponsored program in Maryland, the purpose of which would be to determine, once and for all, whether there is a serious drug abuse problem in Maryland and, if so, what type problem it is, the source of the problem, and solutions. This will be followed in the coming year.

It is expected that the committee will be enlarged in the coming year, and new projects will be introduced. The chairman wishes to thank the current members for their willingness to serve and hopes they will continue their interest.

STEPHEN A. HIRSCH **MD, Chairman**
RALPH E. ALVING **MD**
AUGUSTO DeLEON **MD**
NELSON G. GOODMAN **MD**
J. LEONARD LICHTENFELD **MD**
NOEL D. LIST **MD**
DON M. LONG **MD**
JOHN A. SINGER **MD**
JOHN R. SMITH **MD**
RICHARD F. TYSON **MD**

Emergency Medical Services

Mr. President and Members of the House of Delegates:

The committee decided not to pursue approval of its drafted suggested guidelines for freestanding medical centers in October 1984 shortly after they were submitted to Council for approval. This decision was made because the National Association of Freestanding Emergency Centers was renamed the National Association for Ambulatory Care (NAFAC). The committee agreed that freestanding medical centers should follow the NAFAC guidelines and that freestanding emergency centers should follow the guidelines set by the American Medical Association.

Several legislative bills regarding freestanding facilities were reviewed by the committee during the 1985 legislative session.

Representatives from the Maryland Poison Center attended a meeting to inform the members of the center's activities and services. Suggestions were requested on how the center could better serve the physician population in Maryland.

The Executive Director of the Maryland Institute of Emergency Medical Services Systems also attended a meeting to describe the newly approved shock trauma facility.

JOHN B. DeHOFF **MD, Chairman**
FRANK T. BARRANCO **MD**
BRUCE P. BOLLENS **MD**
ALEXANDER P. CADOUX **MD**
JOSEPH J. COLELLA, Jr., **MD**
SALVATORE R. DONOHUE **MD**
MAX R. ENGLISH **MD**
PETER M. FAHRNEY **MD**
STANLEY Z. FELSENBERG **MD**
JOSEPH A. FORTUNA **MD**
HUBERT T. GURLEY **MD**
JOSEPH H. HOOPER **MD**
HAROLD S. JENKINS **MD**
HARRIETT C. KOPPELMAN **MD**
GARY W. LANGSTON **MD**
J. BRETT LAZAR **MD**
CATHERINE S. MAY **MD**

DAN K. MORHAIM MD
NEVEN A. POPOVIC MD
FAUSTO M. PREZIOSO MD
AMEEN I. RAMZY MD
JEAN M. THORNE MD
CHARLES E. WILES, III, MD

Emotional Health

Mr. President and Members of the House of Delegates:

The Committee on Emotional Health met six times during the 1984–1985 year. Ido Adamo MD maintained active liaison with the Faculty's Committee on Preventive Medicine and Public Health. Stephen Hirsch MD served as chairman of the Subcommittee on Mental Health of the Faculty's Legislative Committee. Samuel Blumenfeld MD represented the Committee in meetings with the Committee on Alcoholism.

The Committee discussed a number of issues facing psychiatrists within the medical community. After careful consideration the Committee formulated a proposal for a mental health column, "Psychiatric Notes," for the *Maryland Medical Journal* as part of an effort to expand the liaison with other medical specialties. *MMJ* has accepted the column as a monthly department and will begin publication with the September 1985 issue. Edited by Lino Covi MD, this column offers useful clinical information to the entire medical community.

The Committee followed with concern the recent personnel transition in the position of Director, State Mental Hygiene Administration. Letters stating these concerns were directed to a receptive and responsible Faculty leadership.

The Chairman appreciates the efforts of the members of the Committee throughout the year. We look forward to continuation in the coming year.

GARY W. NYMAN MD, **Chairman**
IDO ADAMO MD
EMILE BENDIT MD
CHRISTOPHER BEVER MD
MICHAEL BISCO MD
SAMUEL BLUMENFELD MD
ARNOLD BRENNER MD
LINO COVI MD
KENNETH FLIGSTEN MD
STEPHEN HIRSCH MD
IRENE HITCHMAN MD
H. JACK HUDSON MD
PETER KLEIN MD
THOMAS KRAJEWSKI MD
DANIEL KRANK MD
NANCY NICHOLS MD
ALBERT POWELL MD
JAMES QUATTLEBAUM MD
BRUCE REGAN MD
H. L. P. RESNIK MD
BETTY ROBINSON MD
DONALD SLAUGHTER MD
EDWARD SUAREZ-MURIAS MD
NOEL TAYLOR MD
RONALD TAYLOR MD
LEONARD ZULLO MD

Executive Director

Mr. President and Members of the House of Delegates:

April 15, 1985 marked the completion of 27 years of service as your Chief Executive Officer. During that time many changes have occurred in the practice of medicine. We have moved from a period when physicians were not reimbursed for treatment of Medicaid patients to one when physicians are concerned over the amount of payment; from a period when third-party carriers provided payment for only a small segment of the population to the present when more than 50 percent of payments to physicians come from federal and state governments combined and the balance from other third-party payors; from the fee-for-service market that dominated the field of medicine to the present conglomeration of plans such as HMOs, PPOs, IPAs, closed panels, and countless other types of service arrangements for medical care.

Despite all this reorganization, there still is tremendous pressure on physicians, the primary providers of health services, to control the total cost of health care. Some strides have been made in this field, albeit they are not accepted too rationally by many physicians. More and more controls are placed on physicians. It is unfortunate that those who are reasonable chargers must pay the penalty for those who are not.

With an increasing supply of physicians, there is no doubt that competition will continue for patients, their health care dollars, and their loyalty.

Hundreds of physicians through their local and state medical societies are continually trying to find solutions to the many questions and problems that arise. This loyalty to preserving the practice of medicine unhindered by government and other regulations cannot be bought.

Future years will see how successful we have been in controlling our own destiny.

JOHN SARGEANT CAE, **Executive Director**

Finance

Mr. President and Members of the House of Delegates:

The economic recovery was exceptionally strong in the first half of 1984, but shifted to a slow pace in the second half. Weak economic statistics for August, September, and October raised fears of a recession. The final result of our portfolio for the year ended December 31, 1984 was a loss of 1.8 percent, and the market value

was $1,682,002 at year end.

T. Rowe Price expects the economic slowdown to continue through the first quarter, with more rapid growth occurring later in the year. Two important factors suggest more than the usual uncertainty in forecasting the economic environment. Most prominent is the outlook for currency markets. The strength of the dollar has had significant effects on the recent performance of the U.S. economy, holding down inflation and encouraging an inflow of foreign capital. Conditions remain volatile and if the dollar were to fall, interest rates, inflation, and economic growth would be affected, causing a weaker economy. A second uncertainty is the outlook for tax reform. This issue will not be resolved quickly. Meanwhile, organizations are becoming aware of the implications. This uneasy environment could cause a material slowdown in investment and construction.

These and other factors are reasons for caution regarding the stock market. However the potential for the stock market to catch up for its underperformance in recent years is strong and indicates long-term investors should remain committed to equities.

JOSE M. YOSUICO MD, Chairman
LEWIS H. DENNIS MD
GERALD A. GLOWACKI MD
ALFONSO H. JANOSKI MD
ARTHUR T. KEEFE, JR., MD

Finney Fund

Mr. President and Members of the House of Delegates:

Members of the Finney Fund Committee joined with members of the Library and History Committee to attend meetings of the Quinan-Cordell Maryland Medical History Society on September 26, 1984 and on December 12, 1984.

The surgical periodicals purchased for the Faculty Library with income to the Finney Fund in 1985 remained the same as in 1984.

EDMUND C. BEACHAM MD
JUAN G. GAN MD
A. McGEHEE HARVEY MD
JAMES P. McCARRICK MD
PETER VAN B. THORPE MD

Health Planning and Manpower

Mr. President and Members of the House of Delegates:

The Committee on Health Planning and Manpower had no formal meetings this year due to the unusual action by the Governor in establishing a Task Force on Health Care Cost Containment. The significant legislative action growing out of this Task Force is described elsewhere in these reports, and such activity was managed most effectively by the Faculty legislative organization.

Throughout the past year, efforts were continued to monitor the endless amount of information generated by the Health Resources Planning Commission. This Commission has recently restructured its internal staff and reasonable liaison will be established in areas of mutual concern.

As Chairman of the Committee, I did lead a group to analyze the health resources section of the Health Policy Agenda for the American People, developed by the American Medical Association. Comments were provided to the Faculty Delegation to the AMA on issues dealing with health manpower, health care facilities, and health care technology.

The Chairman wishes to express his appreciation to all members of the Committee for their involvement in this activity.

JAMES T. ESTES MD, Chairman
TIMOTHY D. BAKER MD
EDGAR A. BERING MD
MACK BONNER, JR., MD
MAX E. BYRKIT MD
JOHN B. DE HOFF MD
GUNTHER D. HIRSCH MD
JACK R. LICHTENSTEIN MD
WILLIAM C. MORGAN MD
GARY NYMAN MD
STEPHEN K. PADUSSIS MD
GEORGE W. SETTLE MD
JOHN R. SMITH, JR., MD
BALTASAR B. VELEZ MD
WILLIAM A. WARREN MD
JEFFREY C. WEIDIG MD
ISRAEL WEINER MD
KENNARD L. YAFFE MD

Hospital Medical Staffs

Mr. President and Members of the House of Delegates:

This year, the Committee on Hospital Medical Staffs continued to encourage hospitals to elect representatives to the Committee, and membership did increase. However, the Committee will continue to pursue its goal of representation from all Maryland hospitals. The Committee now meets four times a year, with two of the meetings held in conjunction with the Faculty's annual and semiannual meetings. In order to establish continuity, the bylaws were amended to allow staggered 3-year terms and to permit Faculty members to serve on the Committee even though they are not members of the AMA.

In keeping with its recommendation that each hospital establish a working ethics committee, the Committee distributed the Report of the Maryland Hospital

Association's Advisory Committee on Medical Ethics to each hospital medical staff president, stressing the importance of such committees. The Committee also has voted to investigate the possibility of reactivating a mediation program with the Maryland Hospital Association that would offer a mechanism for mediating disputes between hospital medical staffs and hospital administrators.

J. DAVID NAGEL MD, Chairman
JAMES E. BELL MD
MARCO CLAYTON MD
PETER M. FAHRNEY MD
HUBERT L. FIERY MD
THOMAS CIMONETTI MD
MOISES Z. FRAIMAN MD
JEROME HANTMAN MD
LOUIS H. HIMES II MD
GUNTHER D. HIRSCH MD
DEUSDEDIT JOLBITADO MD
CARL HENRY KELLER MD
GAYLORD S. KNOX MD
RALPH LONGWAY MD
RICHARD MANEGOLD MD
FRANCIS MAYLE JR. MD
LESLIE R. MILES JR. MD
ALFRED T. NELSON MD
STEPHEN K. PADUSSIS MD
SAMUEL R. PINES MD
E. MASOUD POUR MD
PAUL E. PRITCHETT MD
WILLIAM J. ROE MD
JAMES ROSBOROUGH MD
BARRY N. ROSENBAUM MD
MIR-AHMAD SARSHAR MD
ROBERT SCHLAGER MD
WILLIAM I. SMULYAN MD
JACK I. STERN MD
BALTASAR VELEZ MD

Members at Large
JOSEPH BERMAN MD
JOSE MARTINEZ MD

Legislative

Mr. President and Members of the House of Delegates:

The 1985 legislative year really began in late 1984 with the Governor's Task Force on Health Care Cost Containment. Weekly meetings of that group were attended by staff as the committee began to shape the ideas that were embodied in the seven administration cost containment bills. The executive subcommittee, composed of physicians Israel Weiner, Stanley Kirson, Paul Burgan, Donald Dembo, Stephen Hirsch, Mehdi Yeganeh, Thomas Pozefsky, J. Andrew Sumner, and Harold Bob, was given the charge of reviewing the government package. Both staff and physician resources were used intensely during the hearing process. The final outcome of this effort was enactment of the following legislation: SB 494, an emergency moratorium on CON applications until October 1, 1985; HB 1070, deducting the cost of medical education and uncompensated care before determining the rates for a "low-cost" hospital to qualify for a prepaid insurance plan; SB 495, streamlines the CON process; HB 1071, a comprehensive utilization review process for all hospital patients; SB 655, incentive for hospitals to merge and consolidate; HB 1072, clarifying the duties of the HSCRC and providing for the collection of physician practice pattern data; and SB 492, licensure for major medical equipment costing in excess of $600,000.

Work has begun with the Department of Health and Mental Hygiene to implement the equipment licensure, utilization review, and physician practice pattern measures. The Faculty is heavily involved in all three activities. A joint oversight committee of the House and Senate will continue a review process of the progress of the legislation and the House Environmental Matters and Senate Finance Committees have begun interim work on other cost containment efforts.

A ten-year effort ended with the passage of a bill permitting hospitals and physicians to honor "living wills" as executed by patients. The bill was brought to final passage with the combined efforts of many legislators, senior citizen groups, and the Maryland Catholic Conference. Lobbyists for the MCC drafted several pages of amendments and, in return for adoption, removed their opposition to the bill.

Freestanding birthing centers will be licensed and freestanding emergency medical care facilities will be required to abide by certain regulations if they advertise services for life-threatening conditions. Newborns will be screened for sickle hemoglobin. This bill builds on pilot projects in place in Maryland. Infants will undergo screening for early identification of hearing impairment. Laboratories will be required to report to local health departments the results of tests indicating blood lead poisoning in children 18 and under.

Two more health-related groups won recognition under Maryland law in this session. Professional counselors will be certified. These will include professional counselors who have attained the level of master's degree or beyond. The bill expressly denies the provision of health insurance benefits for these counselors unless the policy already provides coverage for such services. Similarly, dietitians will be licensed in Maryland. The bill defines the practice of dietetics, and it, too, denies health insurance reimbursement unless the service is already covered by the policy.

All physicians will be required to post a notice in their office informing patients whether they participate in the Medicare program, whether they accept assignment on a case-by-case basis, or whether they do not

participate.

The Commission on Medical Discipline was given additional authority to deny a license to a physician who has been disciplined in another state. Hospital physicians, nurses, physical therapists, and podiatrists will be required to demonstrate an oral competence in the English language for admission to a hospital staff. The various licensing boards for the professions will develop regulations for implementation. Graduation from an English-speaking professional school will be acceptable proof of language competence.

Health insurance will now pay for some expenses involved with in-vitro fertilization. Benefits are limited to married couples with a five-year history of infertility or whose infertility is associated with certain conditions. Preferred provider contracts will have to pay nonpreferred providers at least 80 percent of fee ordinarily paid to the preferred provider under the contract. ERISA plans are exempted from the bill.

All smoking regulation bills were defeated in the House committee, although the bill to eliminate smoking in retail stores was supported by the Retail Merchants Association and narrowly missed passage in the committee. The initiative to require mandatory seat belt use in Maryland was defeated.

In the malpractice area, the Medical Mutual Liability Insurance Society won the right to offer other lines of insurance. However, the omnibus reform bill that addressed the Health Claims Arbitration Office failed on the final night of the legislature for the second year in a row. This bill embodied the suggestions of the Governor's Task Force on Medical Malpractice.

Bills were introduced requiring a breast cancer pamphlet be developed by the state, mandating breast cancer informed-consent forms in hospitals and specifying what information must be given a patient prior to receiving an implant of any kind. These subjects had been discussed during several other sessions of the legislature, and the Faculty had agreed to develop a brochure on breast cancer for statewide distribution. The pamphlet was in the final stages of development when the bill was introduced. The bills failed and the pamphlet will contain expanded information about informed consent prior to breast cancer surgery and language about breast reconstruction. This issue remains one of study for the Environmental Matters Committee during the interim.

The perennial bill to permit optometrists to use diagnostic drugs failed once again as did a bill giving the HSCRC jurisdiction over "ologists."

Members of the legislative committee participated in mock hearing sessions prior to the opening of the legislature. More than 30 physicians practiced testifying before a panel of "legislators" to prepare for possible future testimony in Maryland. The mock hearing program was recognized by the American Medical Association for inclusion in its State Legislative Conference in January. John Sargeant CAE and Elza Davis conducted mock hearing sessions that were attended by physicians involved with state legislation from around the country. Jose Martinez MD assisted by offering critiques of the sessions.

A very successful visitation program was conducted throughout the 90-day session. Members of the legislative committee were asked to attend a session of the General Assembly, listen to a committee hearing, and visit their individual legislators while in Annapolis. Many physicians had the opportunity to see their government in action for the first time.

Once again, the Faculty staffed the First Aid Room. Carolyn McCoy was the nurse on duty throughout the session. According to McCoy, a total of 1,137 patients were seen, representing an increase of 136 patients over the 1984 session. Of these patients, four were sent to the Emergency Room at Anne Arundel General Hospital, one was sent to the Emergency Room at St. Agnes Hospital and admitted there by her own private physician, four were referred to their own physicians, one was referred to a local physician, and one was sent to x-ray at Anne Arundel General Hospital. A total of 58 physicians served as volunteer "Doctor of the Day." Of these, 32 were from the Maryland Academy of Family Physicians, 14 were from the Maryland Chapter, American College of Emergency Physicians, and 12 were from other specialties.

Personal thanks of Jose Martinez MD, Chairman, are extended to all members of the Faculty who have taken the time to become directly involved with the legislative process on behalf of the association. Dr. Martinez steps down after six years as legislative chairman.

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Liaison with the Department of Health and Mental Hygiene

Mr. President and Members of the House of Delegates:

The Committee devoted considerable study to the development of a survey instrument to measure the full costs of treating patients by primary care physicians. This is directly related to recent limitations on Medicaid expenditures for primary care provided by hospital outpatient departments. Several specialty societies are engaged in the collection of appropriate data.

Other Committee activities included the review of Departmental utilization control activities, length of stay criteria for alcoholism detoxification, and CPT-4 coding for psychiatric services. All such issues were thoroughly addressed and satisfactorily resolved.

As Chairman, I extend my sincere appreciation to each member of the Committee for their experience and contribution to this area of Faculty activity.

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Liaison with Third Party Carriers

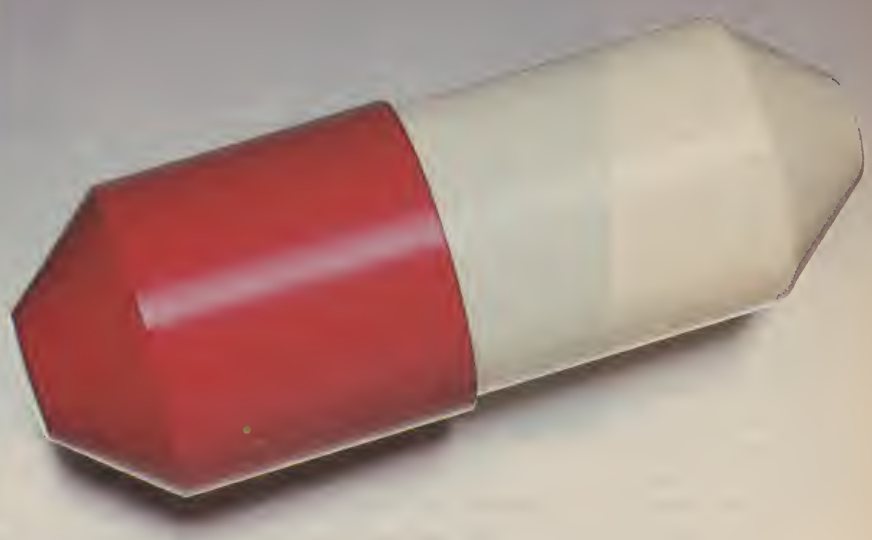
Mr. President and Members of the House of Delegates:

The Liaison Committee with Third Party Carriers continues to seek resolution of specific problems raised by physicians regarding a variety of policies established

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WARNING

This drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spironolactone or amiloride. Further use in anuria, progressive renal or hepatic dysfunction, hyperkalemia. Pre-existing elevated serum potassium. Hypersensitivity to either component or other sulfonamide-derived drugs.

Warnings: Do not use potassium supplements, dietary or otherwise, unless hypokalemia develops or dietary intake of potassium is markedly impaired. If supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter/day, the elderly and diabetics with suspected or confirmed renal insufficiency. Periodically, serum K^+ levels should be determined. If hyperkalemia develops, substitute a thiazide alone, restrict K^+ intake. **Associated widened QRS complex or arrhythmia requires prompt additional therapy.** Thiazides cross the placental barrier and appear in cord blood. Use in pregnancy requires weighing anticipated benefits against possible hazards, including fetal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiazides appear and triamterene may appear in breast milk. If their use is essential, the patient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allergy or bronchial asthma. Possible exacerbation or activation of systemic lupus erythematosus has been reported with thiazide diuretics.

Precautions: The bioavailability of the hydrochlorothiazide component of 'Dyazide' is about 50% of the bioavailability of the single entity. Theoretically, a patient transferred from the single entities of Dyrenium (triamterene, SK&F CO.) and hydrochlorothiazide may show an increase in blood pressure or fluid retention. Similarly, it is also possible that the lesser hydrochlorothiazide bioavailability could lead to increased serum potassium levels. However, extensive clinical experience with 'Dyazide' suggests that these conditions have not been commonly observed in clinical practice. Do periodic serum electrolyte determinations (particularly important in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphotericin B or corticosteroids or corticotropin [ACTH]). Periodic BUN and serum creatinine determinations should be made, especially in the elderly, diabetics or those with suspected or confirmed renal insufficiency. Cumulative effects of the drug may develop in patients with impaired renal function. Thiazides should be used with caution in patients with impaired hepatic function. They can precipitate coma in patients with severe liver disease. Observe regularly for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving triamterene, and leukopenia, thrombocytopenia, agranulocytosis, and aplastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes mellitus. The effects of oral anticoagulants may be decreased when used concurrently with hydrochlorothiazide; dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of nondepolarizing muscle relaxants such as tubocurarine. Triamterene is a weak folic acid antagonist. Do periodic blood studies in cirrhotics with splenomegaly. Antihypertensive effects may be enhanced in post-sympathectomy patients. Use cautiously in surgical patients. Triamterene has been found in renal stones in association with the other usual calculus components. Therefore, 'Dyazide' should be used with caution in patients with histories of stone formation. A few occurrences of acute renal failure have been reported in patients on 'Dyazide' when treated with indomethacin. Therefore, caution is advised in administering nonsteroidal anti-inflammatory agents with 'Dyazide'. The following may occur: transient elevated BUN or creatinine or both, hyperglycemia and glycosuria (diabetic insulin requirements may be altered), hyperuricemia and gout, digitalis intoxication (in hypokalemia), decreasing alkali reserve with possible metabolic acidosis. 'Dyazide' interferes with fluorescent measurement of quinidine. Hypokalemia is uncommon with 'Dyazide', but should it develop, corrective measures should be taken such as potassium supplementation or increased dietary intake of potassium-rich foods. Corrective measures should be instituted cautiously and serum potassium levels determined. Discontinue corrective measures and 'Dyazide' should laboratory values reveal elevated serum potassium. Chloride deficit may occur as well as dilutional hyponatremia. Concurrent use with chlorpropamide may increase the risk of severe hyponatremia. Serum PBI levels may decrease without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. 'Dyazide' should be withdrawn before conducting tests for parathyroid function.

Thiazides may add to or potentiate the action of other antihypertensive drugs.

Diuretics reduce renal clearance of lithium and increase the risk of lithium toxicity.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth; anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions; nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances; postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancreatitis, xanthopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and vertigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitial nephritis have been reported. Impotence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established.

Supplied: 'Dyazide' is supplied as a red and white capsule, in bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); in Patient-Pak™ unit-of-use bottles of 100.

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by insurance carriers. Upon referral by Council, the Committee studied the availability of information on contracts offered to physicians by HMOs, IPAs, PPOs, etc. The Committee and staff focused on many claims-specific problems brought to its attention by practicing physicians, and through such intervention appropriate solutions were achieved.

As Chairman, I extend my sincere appreciation to the members of the Committee and to staff for their contributions in this area of Faculty work.

PAUL BORMEL MD, Chairman
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Library and History

Mr. President and Members of the House of Delegates:

The Library and History Committee met twice during the past year in conjunction with the Quinan-Cordell Maryland Medical History Society.

The highlight of the past year for the Faculty's Library was the acquisition of an IBM PC XT computer in January. The new computer was put to use almost immediately by the Public Services Department. Almost all MEDLINE searches are now run on the computer. The information is transmitted from the National Library of Medicine's computer in Bethesda to the Faculty Library at 1200 baud, in contrast to the 300 baud rate that characterized our former setup. In addition, the information is now captured in our computer's memory where it can later be manipulated and formated into a response to our physicians' questions. This formating is now being done on our own time rather than on time that we pay for while connected to the National Library of Medicine. Both the higher transmission speed and the shorter on-line time have lowered the library's cost for MEDLINE searching.

Along with the new computer, a 2400 baud modem was purchased that allows the library to communicate with the Maryland Legislature's on-line system for keeping track of bills during the legislative session.

Within the coming year, bookkeeping for the Faculty's Library will be entered into the new computer. We also anticipate that our Hospital Library Subscription Service and Book Cataloging and Acquisition Service will be automated using the new computer.

The computer has been useful for Faculty activities outside the library. We were able to use the computer to print the name badges for the Faculty's 1985 annual meeting. Also, the computer is the Faculty's tie to Maryland Med-Sig, a physicians bulletin board operating under the auspices of the Faculty's new Ad Hoc Committee on Computers in Medicine. We anticipate that in the coming year, many additional uses for the new computer in support of Faculty activities will arise.

The library has continued to sustain the level of its services for Faculty members without increases in the operating funds the library receives from the Faculty, even though the costs of health sciences books and periodicals, references materials, and computer on-line time continue to rise. The differences between the level of funding and the operating costs are being met by income raised from marketing all the library's services to individuals, institutions, and corporations not directly connected with the Faculty. The Librarian and Associate Librarian spent approximately thirty five staff days consulting with various hospitals regarding library services at their institutions. Contracts were maintained with five hospitals for long-term consulting services during this year. In addition, the operation of The Chirurgical Bookshop continues to generate income that supports the activities of the Rare Book and History of Medicine Department.

Information and Reference Services

The overall use of the Faculty Library by member physicians remained almost constant during the 1984–85 year both in the number of individual members who used the library and in the volume of services requested by these members. Just over one thousand individual members of the Faculty (one out of every five) called on the library at least once during the past year.

The following table itemizes the volume of information and reference services for 1984–85, compared with the previous year.

Services	1983–84	1984–85
Computerized literature searches	1,327	1,290
Photocopied articles	6,746	8,040
Items borrowed from other libraries	2,355	1,979
Items loaned to other libraries	1,140	1,414
Telephone reference questions	9,192	9,062

The decline in number of computerized literature searches is the result of the same factors discussed last year, the increasing number of hospital libraries who offer computerized literature searching and the increasing number of physicians who have home computers and can do their own literature searching. The decline in the number of searches requested of the library is countered by a dramatic increase in the number of

photocopied articles being requested of the library by physicians and other libraries. Requests for articles by member physicians increased 18 percent in the last year. Requests from other libraries went up 32 percent. As more hospital libraries and individual physicians obtain access to MEDLINE and other information data bases there will be a growing demand placed on the library to provide the original articles.

The significant decline in the number of items for which the library had to obtain copies from other libraries in order to respond to requests for information (down 19 percent over the previous year) continues to demonstrate the effectiveness of the library's periodical acquisition program, inaugurated in 1980. The saving to the Faculty's Library from this program was at least $2,000 in the past year. This figure will continue to grow as more significant back files of the new periodicals are developed.

Fourteen institutions and three individuals maintained subscriptions to the Faculty Library's reference and information services during the past year.

Library Resources

The following table illustrates the growth of the library collection in the past year.

	1983–84	1984–85
Books added	347	245
Journals bound	813	616
Total volumes added	1,160	861
Volumes withdrawn	6	340
Total volumes in collection	108,388	108,909

As pointed out in last years's report, the number of volumes bound in 1983–84 was unusually large due to a lull in our binding operations during 1982–83. This delay was necessary while the library searched for a new binder. In the last year, the library purchased its own periodical binding machine. We will now bind our own periodicals whenever a volume is complete. In addition, Faculty members will no longer have to wait while we obtain a copy from another library for an article in a volume that is out to the bindery.

Last year's annual report stated we would begin a project to weed some of our monograph collection. The project has begun and is reflected in the statistics above. The process is slow because staff time required to remove a book from our collection, delete the records, and dispose of the book is nearly equal to the time required to acquire and catalog a book. The project will continue this year.

During the past year, twenty three hospitals used the Faculty Library's book ordering and cataloging service to maintain their libraries. In addition, six hospitals rely upon the Faculty Library to maintain their periodical subscriptions.

History of Medicine and Rare Books

In 1984–85, the History of Medicine and Rare Books Department responded to questions from 71 visitors. The staff logged 208 books out of the collection for the use of patrons and responded in writing to 52 questions.

One catalog was issued for The Chirurgical Bookshop. Among the items listed for sale were 167 duplicate items that had been withdrawn from the history collection. Income from the sale amounted to $2,281. Donations of books and journals were received from 101 individuals and estates. The value of these donations to the library, were it to attempt to purchase these items, was approximately $53,700.

Several major exhibits were mounted during the year. *Highlights in the History of Maryland's Black Physicians* was the exhibit at the Faculty's Annual Meeting in April in 1984. *From Poison Arrows to Hypodermic Needles: the History of the Syringe* was put in the exhibit cases on the first floor in the Fall of 1984. A previous exhibit, *The Medical and Chirurgical Faculty and the Evolution of Professional Dentistry* was mounted by invitation at the American Dental Association's Annual Meeting in Atlanta in the Fall of 1984.

The Quinan-Cordell Medical History Club hosted two speakers for its meetings during the year. In September, H. Berton McCauley, DDS spoke on "Early Regulation of Dentistry in Maryland." In December, Audrey B. Davis PhD from the Smithsonian Institution discussed "From Tooth Fairy to Tooth Jeweller: The Rise of American Dentistry in the Nineteenth Century."

Staff Activities

The Librarian, Associate Librarian, and Cataloging and Acquisitions Specialist attended the Annual Meeting of the Medical Library Association in Denver, Colorado in May 1984. The Librarian currently serves on the jury for awarding the Association's Murray Gottlieb History of Medicine prize. He is a member of the Consulting Editors Panel for the Association's *Bulletin of the Medical Library Association*. He is also the elected representative of the Medical Society Librarians' Section to the Association's Section Council.

The Librarian, Associate Librarian, and Cataloging and Acquisitions Specialist also attended the Annual Meeting of the Medical Library Association's Mid-Atlantic Regional Chapter in Washington, DC in November 1984.

The Associate Librarian attended the Annual Meeting of the Maryland Library Association in Ocean City, Maryland in May 1984.

The Cataloging and Acquisitions Librarian spoke at the July 1984 meeting of the Constellation Chapter of the American Business Woman's Association. Her topic

was the "History of the Caduceus."

The Reference and Circulation Librarian attended the Annual Meeting of the Special Libraries Association in New York City where she attended a continuing education program on "The Use of Microcomputers in Small Libraries" in June 1984. The Reference and Circulation Librarian was also the speaker at the April meeting of the Baltimore Association of Retired Pharmacists. Her topic was "Occupational Diseases of Musicians."

The Collection Manager for the History of Medicine and Rare Book Collection completed a three-month internship at the Johns Hopkins University Eisenhower Library in July 1984. The internship was funded under a grant from the Mellon Foundation. The Collection Manager also attended the Annual Meetings of The American Association for the History of Medicine and The Association of Librarians in the History of the Health Sciences in San Francisco, California in May 1984. The Collection Manager served as Vice-president of the Baltimore Area Conservation Group in 1984, and was elected President for 1985. She also serves as Co-editor of the Group's newsletter, *The Deckled Edge.*

The entire library staff attended various meetings of the Maryland Association of Health Sciences Librarians when the meeting topic was related to their work activities. The Associate Librarian served as the Association's Vice-president and Program Chairman for 1984–85. The Cataloging and Acquisitions Specialist was elected to the same position for the coming year.

The entire library staff participated in the Faculty's Annual Meeting in April 1985. Bibliographies of recent articles were prepared and distributed by the library staff at each educational session of the meeting. The Collection Manager prepared a historical exhibit entitled *Roast Them, Burn Them, Toast Them: Ultraviolet Radiation Therapy: The Panacea of the 20's and 30's.* The entire library exhibit was well attended by Faculty members.

Plans for 1985–86

Two projects will require most of the library staff's energies during the coming year. We will continue automating the library's operations using programs that run on the new computer. With the beginning of construction on the new Faculty building next door, we will also put into motion the plans for the expansion of the library onto the third and fourth floors of the present building and the expansion of the stack capacity, as described in previous Library Pages in the *Journal* and in last year's annual report.

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MARCO CLAYTON MD
THOMAS B. TURNER MD
CONRAD B. ACTON MD
H. BERTON McCAULEY DDS

Long-Term Care and Geriatrics

Mr. President and Members of the House of Delegates:

The Committee on Long-Term Care and Geriatrics continued its active schedule this past year with emphasis on keeping physicians abreast of rapidly changing issues affecting the elderly. The Committee met with the Acting Chief of the Division of Long-Term Care of the Medical Assistance Program regarding an up-date on medicaid reimbursement. Additionally, the Committee met with the Coordinator of Elderly Services of the Harbel Community Mental Health Center with regard to services available through that facility. Thomas F. Krajewski MD, Assistant Secretary for Health, was present to respond to this issue.

Information was presented to the Committee from the Maryland Health Resources Planning Commission on the issue of Mental Health and the Elderly. The Long-Term Care Director of the Delmarva Foundation presented an up-date to the Committee on that Foundation's recent contract with Medicaid for utilization review of Long-Term Care facilities. Also, the Committee established liaison with the newly appointed Chief of the Division of Licensing and Certification with regard to the Task Force on Nursing Home Regulations. Throughout the year, the Committee has continuously followed the Governor's Commission on Alzheimer's Disease and Related Disorders.

In May, approximately twenty five medical directors of the long-term care facilities attended the seventh annual medical director's meeting and heard detailed presentations concerning pertinent socioeconomic issues. Delegate Larry Young was present at this meeting to address the impact of recent legislation on health care cost containment.

In closing, I extend my sincere appreciation to the members of this Committee who have given their valuable time and services to these important matters.

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Maryland Medical Journal

Mr. President and Members of the House of Delegates:

This report covers the period August 1984 to August 1985, a period marked by the continued excellent health of the *Journal.* With the January 1985 issue, the *Journal*'s name changed to *Maryland Medical Journal*, the same title used from 1877 to 1918. While the cover underwent a dramatic face-lift, the inside of the magazine had more subtle style changes.

A national advertising sales campaign started in 1984, and space sales exceeded those of 1983 by 15.97 percent, with most of the increase occurring in the second half of the year. For the first three months of 1985, sales were up by 72.3 percent over 1984. Our local advertising sales continue to be excellent, and careful monitoring of production costs by the Managing Editor assures the *Journal*'s financial stability. Waverly Press continues to provide a satisfactory local printing service.

With the July 1984 issue the *Journal* assumed publication of the "Disease Control and Epidemiology Newsletter," which had been published by the State of Maryland. Its editors are members of the State Health Department who have accepted the obligation of providing material each month for the *Journal.*

The third annual series sponsored jointly by the Arthritis Foundation Maryland Chapter, Maryland Society for the Rheumatic Diseases and The Johns Hopkins Multipurpose Arthritis Center began in September 1984. The overall topic is Arthritis, and the series editor is Marc C. Hochberg MD.

In November, the Public Relations Committee began a column, "Inside Med-Chi," to be written by various staff members and coordinated by Nina Casey, Publication Relations/Staff Membership Coordinator.

The January 1985 issue, in addition to introducing its new name and format, was devoted to cancer prevention. This special issue was prepared by the Center for Health Education, Inc. working with the National Cancer Institute. NCI ordered 10,000 copies of a 56-page reprint of all the articles for national distribution.

The May 1985 issue featured five articles on pediatric cardiology, taken from a recent symposium sponsored by the Maryland Chapter of the American Academy of Pediatrics.

With the June issue, the Committee on Physician Rehabilitation began a column, "The Impaired Physician." The Emotional Health Committee proposed a monthly mental health page, "Psychiatric Notes." We look forward to reviving the MIEMSS column on a semiregular basis.

Approximately 86 scientific manuscripts were reviewed during the past year. The manuscript rejection rate was 23 percent, just slightly higher than last year's, indicating a continuing need for higher quality scientific manuscripts.

The Editorial Board met on three occasions during the past year to consider items that merited group attention.

All those associated with the production of the *Journal* continue to welcome comments from Med-Chi members regarding any and all facets of the *Journal.* As has always been the case, the basis for any editorial decision will be shared with anyone having an interest in the *Journal.* The Editorial Board and the Managing Editor thank the many outside reviewers of manuscripts who have so graciously donated their time and expertise in assisting the Editorial Board in this important function over the past year.

JAMES G. ZIMMERLY MD, Editor
VICTOR R. HREHOROVICH MD, Associate Editor
RICHARD BAUM, MD
JAMES P. G. FLYNN MD
PHILLIP J. GOLDSTEIN MD
FREDERICK HELDRICH MD
FRANK L. IBER MD
LOUIS KOZLOFF MD

Med-Chi Insurance Fund

Mr. President and Members of the House of Delegates:

The Med-Chi Insurance Fund directors met six times in 1984 to carry out their responsibility of monitoring sponsored insurance programs and directing the operations of the Med-Chi Agency.

The Hartford plan of Major Medical and Weekly Disability coverage was improved in 1984. The limit on the Major Medical plan was increased to $250,000, and the limit on the disability was increased from $480 per week to a new maximum of $1,140 per week.

The Agency is providing $5,000 life insurance at no cost to each member of the Resident and Student component societies of the Faculty. This membership benefit should help in the recruitment and retention of Faculty members.

The Med-Chi Agency is the Franchised Broker for the Medical Mutual Liability Insurance Society in Baltimore City, Baltimore County Metropolitan area. This is one of eight franchises in the State of Maryland. The franchise gives the Agency some exclusive marketing information and results in greater market penetration and earnings.

A new physician loan program has been established by the Agency. Under this program, a new physician can obtain a loan up to $100,000 at an interest rate of 2 points over prime. No co-signer is required and no assets are required. The payment schedule is very lenient.

The Med-Chi Agency enjoyed another financially successful year in 1984. Participation increased and profits were realized, which will benefit the entire Faculty membership. Continued enthusiastic participation by the members will enable the Med-Chi Insurance Fund directors to make the Agency's products and services for doctors the finest in Maryland.

W. KENNETH MANSFIELD MD, Chairman
ADRIAN M. COHEN, MD
WILLIAM J. R. DUNSEATH MD
PAUL F. GUERIN MD
DONALD T. LEWERS MD
RICHARD F. MOSCHELL MD
JOSE M. YOSUICO MD
JOSEPH J. HARRISON, Secretary

Medicine and Religion

Mr. President and Members of the House of Delegates:

The committee held five meetings during the past year. The Second Annual Prayer Luncheon was held on April 25, 1985 during Med-Chi's 187th Annual Meeting. The Reverend Grady F. W. Barbour gave a presentation entitled, "Pastoral Care: Profession, Plebeian Career, or Placebo?" Reverend Barbour is the Episcopal Chaplain at the Johns Hopkins Medical Institutions and a Clinical Supervisor of the Association of Clinical Pastoral Education.

A survey of sixty hospitals in Maryland was conducted by the committee regarding policies related to "No Code" and "Brain Death" guidelines. These are the results:

No Code Guidelines

Of the hospitals responding, 13 (72 percent) currently have a policy. Of the 13, the following is a breakdown of the procedures:

	Number	Percent
1. An order must be written	13	100
2. An order may be given orally	3	23
3. A periodic review is required	4	30
4. Provision for rescinding the order	4	30
5. There must be written documentation of reasons for the order	9	69
6. Policy provides for a review committee (ethics)	3	23

Brain Death Guidelines

Of the 18 responses, 6 (33 percent) have a policy.

1. The policy defines a clinical definition	6	100
2. The policy provides for child situation	2	33
3. Consultation is required	5	83
4. Time element is required for re-evaluation	2	33

The committee believes these figures should be much higher, if not 100 percent. In these times with the high cost of medical care and a large part of this expended in the last 30 days of life (possibly on terminal cases), establishment of criteria is essential. Death with dignity is not to be overlooked.

LESLIE R. MILES, JR., MD, Chairman
CHERYL D. BROWN-CHRISTOPHER MD
JOHN R. HANKINS MD
THOMAS C. HILL MD
BARRY K. LANCE MD
GIBSON J. WELLS MD
MILTON D. WESTBERG MD

Medicolegal

Mr. President and Members of the House of Delegates:

This past winter and spring the Medicolegal Committee, sponsored jointly by the Medical and Chirurgical Faculty of the State of Maryland, the Maryland State Bar Association, and the Baltimore City Bar Association, has been busy. It has continued its prior service to the legal and medical disciplines by considering and making recommendations in disputes by and between attorneys and physicians. In addition to rendering advisory opinions in complaints from either discipline, it has conducted a number of binding arbitrations under a new method of dispute resolution that became effective in early 1984. These arbitration matters are conducted by an arbitration panel of one physician and one attorney who investigate and consider a

complaint and then make a final ruling ending the matter. This procedure is voluntary, but the decision is binding.

The Committee presented a program at the Annual Meeting on Friday, April 26, 1985, on "The Evaluation, Treatment, and Trial Demonstration of Traumatic Chronic Pain." This included direct and cross examination of four physicians from the Johns Hopkins Pain Clinic and a panel of physicians and attorneys, with an overview by Judges Corderman and Ross. This program also was presented at the Annual Meeting of the Maryland State Bar Association on January 11, 1985.

The Committee still is working to perfect a form of Authorization and Assignment to be used by attorneys and physicians in connection with the release of medical information, and a form approved by this Committee recently has been submitted to the Boards of Governors of the Maryland State Bar Association and the Baltimore City Bar Association. We are awaiting their comments.

The Committee continues to explore establishing a relationship with the Maryland State Dental Association to bring dentists within the scope of activities of our Committee. The Dental Association has designated three of its members to work with the Committee toward this end.

Other ongoing Committee work includes: the continuation of a medicolegal "hot line," which appears in our publications to assist in resolving disputes of an emergency nature; providing guidelines to attorneys and physicians concerning expert physician testimony and reports; following current legislation; publicizing advisory and arbitration decisions of the Committee and its arbitrators; resolving disputes between State's Attorneys and physicians called to testify in criminal cases; resolving the problems of subpoenas to medical residents at teaching hospitals; and the matter of payment of claimant's physicians in Workmen's Compensation matters.

The Committee's Executive Board continues to meet between meetings of the Committee as a whole.

DONALD M. BARRICK MD, Co-Chairman
BAYARD Z. HOCHBERG Esq., Co-Chairman
BRUCE P. BOLLENS MD
ELLIOTT F. FISHEL MD (Deceased)
ROBERT O. KAN MD
ARTHUR KAUFMAN MD
CURTIS MARSHALL MD
VINCENT O'DONNELL MD
EUGENE H. OWENS MD
DAVID R. PADRINO MD
LYNN A. RIDER MD
JANE O. SEELY MD
ISRAEL H. WEINER MD
AUGUSTUS F. BROWN IV Esq.
PHILIP A. DALES III Esq.
WILLIAM H. ENGELMAN Esq.
JOHN WHEELER GLENN Esq.
MAX R. ISRAELSON Esq.
H. ALBERT KORN Esq.
PEGGY R. ODICK Esq.
JEANNETTE PLANTE Esq.
JOHN L. SCARBOROUGH Esq.
VICTORIA E. SELPH Esq.
ROGER W. TITUS Esq.
PATTI D. GILMAN ZIMMERMAN Esq.

Nominations

Mr. President and Members of the House of Delegates:

For presentation to the House of Delegates, Thursday, April 25, 1985. (Those elected will assume office at conclusion of the Annual Meeting, 1986, unless otherwise indicated.)

President-elect:
Donald T. Lewers, Easton, Talbot County
(President-elect, 1985–86)
(President, 1986–87)

First Vice-President:
John B. Umhau, Jr., Chevy Chase, Montgomery County

Second Vice-President:
Reynaldo L. Lee-Llacer, Clinton, Prince George's County

Third Vice-President:
Leslie R. Miles, Lonaconing, Allegany County

Secretary:
Raymond M. Atkins, Baltimore, Baltimore City

Treasurer:
Jose M. Yosuico, Laurel, Baltimore City

Committee on Scientific Activity (6-year term)
Jose Martinez, Lutherville, Baltimore County (1986–1992)

Library and History Committee (5-year term)
Thomas E. Hunt, Baltimore, Baltimore City (1986–1991)

Finney Fund Committee (5-year term)
John H. Hebb, Baltimore, Baltimore County (1986–1991)

Board of Medical Examiners (4-year term)
C. Earl Hill, Pasadena, Anne Arundel County
(July 1, 1985-June 30, 1989)
Rose M. Bonsack, Aberdeen, Harford County
(July 1, 1985–June 30, 1989)

Delegates to the AMA
Charles F. O'Donnell, Towson, Baltimore County
(January 1, 1986–Dec. 31, 1988)
Michael R. Dobridge, Silver Spring, Montgomery County
(January 1, 1986–Dec. 31, 1988)

Alternate Delegates to the AMA
Joseph Snyder, Silver Spring, Montgomery County (January 1, 1986–Dec. 31, 1988)
Hilda I. Houlihan, Salisbury, Wicomico County (January 1, 1986–Dec. 31, 1988)

Nominating Committee
ROLAND T. SMOOT **MD, Baltimore, Chairman**
ALBERT M. ANTLITZ **MD, Baltimore, Baltimore City District**
CLARENCE E. McWILLIAMS, JR. **, MD, Reisterstown, Balto. Co. District**
JOSEPH SNYDER **MD, Silver Spring, Montgomery County District**
JACK C. MESHEL **MD, Hyattsville, Prince George's County District**
ALEX AZAR **MD, Salisbury, Eastern District**
LESLIE R. MILES **MD, Lonaconing, Western District**
GEORGE H. WATHEN **MD, La Plata, Southern District**
GEORGE E. LINHARDT JR. **, MD Annapolis, Member-at-Large**

Occupational Health

Mr. President and Members of the House of Delegates:

The committee held seven meetings during the 1984–85 year. Council authorized the committee to develop:

1. guidelines for disability evaluation
2. standards for types of evaluations for basic reports and what information should be included
3. standards the individual physician should follow when performing the disability evaluation

The committee's draft, "Suggested Guidelines for what Should be Included in an Impairment/Disability Evaluation Report" has undergone several revisions and should be presented for Council's approval in the near future.

The Ad Hoc Subcommittee on Medicine, Employee, and the Workplace was recently restructured, and Roland T. Smoot MD was appointed chairman. The subcommittee is reviewing employee absence abuse with representatives from industry.

The committee also cosponsored a session at the annual meeting entitled, "The Physician, His Patient, and the Workplace."

The committee expresses its deep regret for the recent loss of Elliott R. Fishel MD, who was a long-standing member of the committee. The time and devotion put forth by Dr. Fishel for the committee is greatly appreciated.

MICHAEL K. SPODAK **MD Chairman**
TIMOTHY D. BAKER **MD**
HERBERT L. BLUMENFELD **MD**
PETER CHODOFF **MD**
ADOLFO CORREA-VILLASENOR **MD**
JOSE B. CORVERA **MD**
ELLIOTT R. FISHEL **MD (deceased)**
JAMES FRENKIL **MD**
MARK L. FRYDENBORG **MD**
SIDNEY R. GEHLERT, JR. **, MD**
DEBORAH L. GOLDBERG **MD**
J. MICHAEL HAMILTON **MD**
ENRIQUE A. HERRERA **MD**
FERDINAND G. MAINOLFI **MD**
EMMANUEL M. MANIAGO **MD**
CHRISTIAN S. MASS **MD**
JOSE G. PUIG **MD**
MARK A. REISCHER **MD**
NORMAN B. ROSEN **MD**
HENRY S. SABATIER **MD**
KATHERINE A. SAMUELS **MD**
HENRY M. SCAGLIOLA **MD**
ROSE M. SESSOMS **MD**
REZA SHAYESTEH **MD**
ANDREW S. TEGERIS **MD**
JOSEPH A. THOMASINO **MD**
EDWIN W. WHITEFORD **MD**

Peer Review

Mr. President and Members of the House of Delegates:

The committee continued to meet monthly, discussing individual problems at each session. While new names are presented to the committee, we are chagrined that some of the people previously reviewed are referred again. In fact, much of the work of the committee is involved with repeated review of records and even second site reviews of physicians who are on probation by the Commission, requiring monitoring of their practices.

Much attention has been given to the preparation of reports and recommendations to the Committee on Medical Discipline. It is becoming increasingly obvious that solid spade work must be done by investigative committees in order for disciplinary recommendations to be carried through the legal process. Since the meeting between physicians serving on peer review committees of Med-Chi and component societies and members of the Commission on Medical Discipline in the past year, there has been a better understanding of each other's problems.

As in past years, most of the committee's referrals were from the Commission on Medical Discipline. A record of the committee activities shows:

Cases referred from Commission (new and referrals)	16
Physicians interviewed and/or records reviewed	24
On-site review	11
Referrals from other sources	9

Recommendations from the committee reflect:

Revocation of license	2
Other (additional education, limitation of practice, etc.)	7
No disciplinary action	5

These figures reflect more than one category in a single review in many cases. In addition, the figures do not reflect those cases referred directly to component societies, or single patient complaints that are referred to another committee for resolution.

As in the past, specialty societies have been extremely helpful in the investigation of cases. It is impossible to have every specialty represented on the committee, making it imperative that such review services are available from the specialty societies. Our gratitude is expressed for past services and anticipated future services.

The chairman expresses his appreciation to all members of the committee for the excellent meeting attendance, but more than that, for their giving their time to make site visits and to review records. These are tedious and often thankless tasks, but absolutely necessary to the process. The medical profession can be proud of its record of "watchdogging" the quality of care and its positive reaction to complaints and reports of substandard practice.

Appreciation is also expressed to Med-Chi staff for its genuine interest and attention to administrative detail.

WALTER J. ALT MD, Chairman
JOSEPH I. BERMAN MD
EMIDIO A. BIANCO MD
WILLIAM A. CASSIDY MD
LIEBE S. DIAMOND MD
MICHAEL J. DODD MD
ELLIOTT R. FISHEL MD (deceased)
EARLIE H. FRANCIS MD
GEORGE H. HENNING MD
MAHER W. ISHAK MD
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EUGENE R. McNINCH MD
JEROME P. REICHMISTER MD
EDWARD J. RICHARDS MD
ERNESTO RIVERA MD
SIDNEY B. SEIDMAN MD
GERALD P. STERNER MD
LARRY G. TILLEY MD

Physician/Patient Relations

Mr. President and Members of the House of Delegates:

The Committee continued its regular monthly meeting schedule to review individual complaints against physicians that were received independently by the Faculty or through formal referral from the Commission on Medical Discipline.

With no exceptions, the investigations performed by this Committee are done thoroughly, objectively, and in accordance with mandated responsibility. The past year has seen an 18 percent increase in cases referred for investigation by the Commission on Medical Discipline. Cases examined by the Physician/Patient Relations Committee are represented as follows:

Cases referred from the Commission on Medical Discipline	250
Cases referred from other sources	23
Professional Corporation (PA) designation reviewed	17
Grievances between physicians	11

Not included in the summary are innumerable discussions with individual physicians, the general public, public policy makers, and others regarding the legal and ethical responsibilities of physicians. With such interpretations, the Committee provides clear and reasonable information and, at the same time, ensures the highest standards of care.

As Chairman, I extend my sincere gratitude to each member of the Committee for countless hours of dedicated work on this essential area of Faculty activity.

LOIS E. WEHREN MD, Chairman
RAYMOND M. ATKINS MD
JACK D. FRANCIS MD
DEAN GRIFFIN MD
DANILO G. LEE MD
SIDNEY MIR MD
JOHN C. PAYNE MD
DAVID B. POSNER MD
BENJAMIN ROTHFELD MD
LEX B. SMITH MD
W. HADDOX SOTHORON MD
JOSE M. YOSUICO MD
JAMES G. ZIMMERLY MD

Hotline Numbers for Impaired Professionals

Physicians—727-0120
Dentists—859-0667
Attorneys—685-7878
Pharmacists—727-0746 or 528-7513

Emergency Psychiatric Beds 800-492-0610

Physician Rehabilitation

Mr. President and Members of the House of Delegates:

The committee met monthly during the past year, with gratifying attendance of the members, some of whom come from distant parts of the state. Much of the meeting time was devoted to reviewing the status of physicians in the program and developing courses of continuing treatment. A statistical breakdown of physicians in the program is shown in the table.

Monitors were assigned to each physician in the program so that the followup procedure could be more equitably shared. A subcommittee was assigned the task of revising the Protocol of the committee to bring it into conformance with current practice and to clarify certain areas.

The Hot Line number for the reporting of impaired physicians has been replaced with a new number connected directly to the person staffing the committee, and with the added advantage of an answering machine, callers may reach a committee member during off-hours or leave a message 24 hours a day. The new number is **727-0120** and members are urged to use it if they have information concerning a physician who may be in need of assistance from the committee because of addictive or psychiatric illness.

Several legislative items came to the attention of the committee during this session of the State Legislature. The bill that would have affected this committee the most would have allowed the state to form an Impaired Physician Committee, funded by the state and requiring certain disclosures. The bill was strongly opposed by the Faculty and the Commission on Medical Discipline, and it failed passage.

A major advance of the committee in this year was the hiring of a half-time committee Coordinator. This is important because the Coordinator is a certified Alcoholism Counselor and will be of great assistance to the committee in verifying reports, setting up interventions, following up on physicians in the program, and generally relieving committee members of a great deal of the leg work necessary in such a program. He also will be available for educational programs in hospitals and the community. It is hoped that this new employee will be funded by an additional member assessment approved by the House of Delegates. The loan program continues to assist many physicians, and pay-backs are improving. Five physicians have taken advantage of this loan opportunity this past year.

The Maryland Veterinary Medical Association requested whatever assistance this committee might be able to give in setting up its impaired veterinarian committee. Advice was given and offer of further assistance if requested. It was learned that the Impaired Nurses Program was discontinued due to financial problems.

The Sixth National Conference on the Impaired Physician was held in Secaucus, NJ sponsored by the AMA. Several members of the committee and Connie Townsend attended the meeting. All agreed the meeting lived up to the standard of excellence of past meetings. Attendees returned with many ideas for improvement of the Maryland program.

The chairman has announced that he will withdraw as chairman of the committee and wishes to thank each member for his or her devotion, expenditure of time and energy, and contribution to the success of the program. Appreciation is expressed to Med-Chi staff for attention to administrative detail and general assistance to the committee.

JOSEPH F. CHAMBERS **MD, Chairman**
H. PATRICK ADAMS **MD**
RICHARD H. ANDERSON **MD**
CHARLES BAGLEY **MD**

Record of Physicians Reported to Committee, February 1985

	1978	1979	1980	1981	1982	1983	1984	Total
1. Improved or recovered	17	12	13	14	11	7	1	75
2. Currently in treatment or evaluation	1	3	3	6	6	8	14	41
3. Refused assistance or returned to abuse	4	5	1	4	7	3	3	27
4. Retired or left state	7	6	5	4	4	2	5	33
4a. Deceased	9	2		1		3		15
5. Unconfirmed		6	5	6	6	5	9	37
6. Referred to Peer Review	1	1	4			2		8
	39	35	31	35	34	30	32	236
Type of Illness								
1. Alcohol	15	18	15	26	18	13	11	116
2. Drugs	10	7	8	3	7	6	10	51
3. Alcohol and drugs	5	2	3	1	2	1	2	16
4. Psychiatric	8	8	5	4	7	10	9	51
5. Physical	1			1				2
	39	35	31	35	34	30	32	236

TIMOTHY BARILA MD
MICHAEL J. BISCO MD
HAZEL CHAMBERS
IRVING A. COHEN MD
GEORGINA Y. GOODWIN MD
JOHN D. GRISWOLD MD
MICHAEL G. HAYES MD
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HECTOR RAMIREZ MD
SISTER MARY THOMAS
MAXWELL WEISMAN MD
CHARLES L. WHITFIELD MD
MAURICIO ZEPLO MD

Consultants
RICHARD MATTHEWS MD
EDSON B. MOODY MD
ROBERT B. TAYLOR MD
EDWARD A. THOMPSON MD
MARTIN J. VALASKE MD

Preventive Medicine and Public Health

Mr. President and Members of the House of Delegates:

The Committee on Preventive Medicine and Public Health met five times during the 1984–85 year. The following items were discussed and acted on by its Subcommittees:

The Subcommittee on Immunizations and Infectious Diseases has taken action on and/or discussed the following items:

1. Continued review of the prevalence of AIDS in Maryland.
2. Approval of a revised draft on the Recommended Schedule of Immunizations.
3. Possibility of purchasing vaccines in bulk.
4. Reviewed a publication for the Department of Health and Mental Hygiene on venereal disease.
5. Examination of the DPT and Pertussis Vaccine shortage.
6. Reviewed pertinent legislative issues before the 1985 General Assembly.

The Subcommittee on Infant, Child, and Adolescent Health has taken action on and/or discussed the following items:

1. Changed the name of the Subcommittee to better identify the issues and concerns of the group.
2. Greatly concerned with the effect on the care and health of a child as well as the physician/patient relationship whenever PPOs are incorporated. Felt the whole concept of PPOs was detrimental to the young patient.
3. Supported the first state conference on teenage pregnancy and parenting.
4. With the recent shortage and expense of the DPT and Pertussis vaccine, the Subcommittee believed steps should be taken to guarantee a supply of vaccine to prevent an epidemic as well as to insure adequate coverage by the state for damage and resultant litigation from DPT vaccine.
5. Created recommendations that would monitor day care centers with pre-employment screening of all personnel and remedial programs for parents.
6. Co-sponsored a program for the 1985 Annual Meeting with the Maryland Chapter, American Academy of Pediatrics.
7. Reviewed pertinent legislative issues before the 1985 General Assembly.

The Subcommittee on Maternal Welfare has taken action on and/or discussed the following items:

1. Continued review of maternal deaths in the State of Maryland.
2. Standards for Outpatient Second Trimester Abortions were revised and sent to Council.
3. Reviewed pertinent legislative issues before the 1985 General Assembly.

Reactivation of the Sports Medicine Subcommittee will take place. William B. Howard MD was named Chairman.

A request from the Committee was submitted to the Auxiliary to investigate the possibility of establishing a health education workshop for teenagers in Maryland. The Auxiliary felt that they could not do this single-handedly but would be able to assist if such a workshop materialized.

Extensive discussion took place on the possibility of changing the law concerning the sale of tobacco to minors under fifteen. Documentation on the hazards of smoking was directed to Council and in turn the Legislative Committee for review.

The Committee sponsored a program at the 1985 Annual Meeting. Edward Brandt MD, Chancellor of the University of Maryland (Baltimore Campus), was the speaker. The Committee reviewed all pertinent legislative issues before the 1985 General Assembly.

VINCENT D. FITZPATRICK MD, Chairman
IDO ADAMO MD
ROBERT ANCONA MD
HECTOR P. C. ASUNCION MD
TIMOTHY E. BAINUM MD
RUDIGER BREITENECKER MD
JOAN COLFER MD
JAMES P. DURKAN MD
FRANKLIN T. EVANS MD
WILSON L. GRUBB MD
JOHN A. HAWKINSON MD
LEROY E. HOECK MD
IRVING A. KESSLER MD
JOHN M. KRAGER MD
RICHARD C. LANG MD

J. BRETT LAZAR MD
JULIUS LOEBL MD
WILLIAM B. MAREK MD
WILLIAM J. MORGAN MD
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DAVID M. PAIGE MD
JOHN L. PITTS MD
THOMAS REICHELDERFER MD
J. COURTLAND ROBINSON MD
DONALD J. ROOP MD
EDWARD A. SAWADA MD
HENRY M. SCAGLIOLA MD
ABRAHAM SCHNEIDMUHL MD
RUTH L. H. SINGER MD
ANDREW T. WILEY MD
ANNELIES S. ZACHARY MD

Advisory Member
JAMES TENNEY MD

Professional Ethics

Mr. President and Members of the House of Delegates:

The Committee on Professional Ethics continued its hard work by tackling a number of tough issues this year. Ethical opinions were either developed or rewritten and approved by Council concerning the following subjects: abandonment, x-rays and charges for transfer, disclosure of office policies, payment for services rendered by two or more physicians and advance payment for medical services. The Committee also has developed guidelines concerning the decision to terminate medical care and guidelines concerning conflict of interest for Faculty officers. The Committee is currently developing an ethical opinion concerning second opinions.

This past year also saw the publication of a completely revised and updated *Compendium of Laws, Regulations, Opinions and Policies Governing the Practice of Medicine in Maryland.* This Committee will continue to review the *Compendium* and provide new ethical opinions when needed.

LOUIS C. BRESCHI MD, Chairman
EDILBERTO BELTRAN MD
WILLIE C. BLAIR MD
EUGENE GUAZZO MD
JOHN S. HAUGHT MD
LESLIE R. MILES JR., MD
MARVIN SCHNEIDER MD
FRANK F. SCHUSTER MD
VERNON SMITH MD
JAMES ANDREW SUMNER MD

Public Relations

Mr. President and Members of the House of Delegates:

The Public Relations Committee had a very exciting and productive year. The committee successfully implemented the 1984–85 long-range public relations plan that included a joint project with the State Office on Aging to promote the patient medication information effort, and a new *Journal* column, "Inside Med-Chi," that is targeted to the membership informing them of Faculty activity and committee work. In an effort to keep Component Societies abreast of Faculty public relations initiatives, we began mailing meeting notices and monthly committee minutes to Component Society Presidents, Executive Directors, and Public Relations Chairmen.

The Council approved a more ambitious plan for 1985–86 that introduces a number of new objectives in addition to continuing those established in 1984–85. Some of the new projects include implementing a media awards program, exploring the possibility of a health program on cable television, and publishing a public relations newsletter in the *Journal.*

The Faculty's radio talk show, "Consultation," enjoyed another successful year. The program is broadcast every other Wednesday from 10 to 11 a.m. on WBJC-FM, 91.5 mHz. Some topics covered were teenage depression, heart attack prevention, and sports medicine. The Faculty also continued to sponsor a radio program on WCBM with Albert M. Antlitz MD as the medical consultant for 1984–85.

Last October the Faculty launched a campaign to contact former graduates of the School #49 accelerated program to inform them of the renovation of their alma mater. The response was overwhelming, and as a result of the enthusiasm and nostalgia for School #49, a committee of former students was organized to plan a reunion. A history of the school is being developed, and the Faculty will be sending a newsletter periodically to keep the graduates abreast of renovation progress and reunion plans.

The committee sponsored a session at the Annual Meeting, "PRO: How It Will Affect Your Patients." The session examined the effect of Maryland's Peer Review Organization on Maryland patients from both federal and state perspectives. John Denion, Chief of the Medical Review Branch for the Health Care Financing Administration, gave an overview of PRO from a national perspective. Patricia McGuire, Assistant Director of the Department of Federal Affairs for the American Medical Association, provided an overview of PRO from the AMA's perspective. Finally, Bert Harrell, Executive Director, Maryland Foundation for Health Care and Leon Kassel MD, Board of Directors,

Maryland Foundation for Health Care spoke specifically of the Maryland experience to date.

During the Annual Meeting, the House of Delegates adopted Resolution 2A/85, Improving the Public's Perception of Physicians, which has been forwarded to the Public Relations Committee to implement. The Committee is responsible for developing and directing "an effort toward improving and maintaining positive relationships between individual patients and their physicians and to coordinate the activities of local medical societies in this endeavor."

JAMES E. BELL MD, Chairman
WILLIAM CASSIDY MD
WILLIAM J. DUNSEATH MD
WILLIAM DVORINE MD
ANTONIA GALINDO MD
BARRY S. GOLD MD
SURYABALA GOSWAMI MD
JEFFREY H. HELLMAN
ENRIQUE A. HERRERA MD
ALFONSO H. JANOSKI MD
ANTOINE E. KFURI MD
KEACIEL K. KRULEVITZ MD
FRED MAGAZINER DDS
AKBAR G. MATADAR MD
DAN K. MORHAIM MD
N. EDWARD NACHLAS MD
HIROSHI NAKAZAWA MD
ALPHONSUS O. OBAYAWANA MD
ROBERT RUDERMAN MD
GHOLAM R. SADJADI MD
REZA SHAYESTEH MD
NEIL SOLOMON MD
A. OMAR VENTO MD
THERESA M. VOGEL MD
ALLAN Y. WOLINS MD
ADRIANA ZARBIN

Reference

Mr. President and Members of the House of Delegates:

The Reference Committee met on Thursday, April 4, 1985 to consider two resolutions. Notices had been sent to all Delegates, Alternate Delegates, Component Society officials, as well as officers of the Faculty. In addition, all Faculty members were notified of this hearing by postcard well in advance of the meeting date. Approximately 30 members were present for the meeting.

Resolution 1A/85

Whereas, In keeping with the bylaws of the Medical and Chirurgical Faculty, the President of the Medical and Chirurgical Faculty has appointed a Committee on Utilization and Quality Control Peer Review to "act as an analytical group to review the effect of programs carried out by the Maryland Foundation for Health Care with respect to the cost and quality of medical care";

Whereas, The Maryland Foundation for Health Care has been designated Professional Review Organization (PRO) for the State of Maryland;

Whereas, In that capacity the Maryland Foundation for Health Care has disseminated a document including a list of surgical procedures that must be performed for Medicare patients on an outpatient basis and a list of diagnoses and/or symptoms that must be investigated in Medicare patients on an outpatient basis;

Whereas, In many instances, denying these patients investigation and/or surgical treatment on an inpatient basis is incompatible with an appropriate quality of medical care and might endanger the lives of many of these elderly patients;

Whereas, Some members of the Board of Directors of the Maryland Foundation for Health Care deny knowledge of such a list of surgical procedures and diagnoses for denial of inpatient hospital care prior to its dissemination by the Maryland Foundation for Health Care; and

Whereas, These lists of surgical procedures, diagnoses and symptoms for denial of inpatient care were assembled and disseminated by the Maryland Foundation for Health Care without adequate consultation with appropriate specialty societies and groups; now therefore, be it

Resolved, That the Medical and Chirurgical Faculty, representing the physicians of Maryland, rejects as arbitrary and inappropriate the Maryland Foundation for Health Care document containing a list of surgical procedures and diagnoses or symptoms for which inpatient hospital care is denied; and be it further

Resolved, That the Medical and Chirurgical Faculty, concerned that the quality of medical care not be sacrificed in the name of cost containment, urges that any future such restrictive policies be disseminated and implemented only after adequate consultation with appropriate specialty societies and groups.

This resolution was submitted by 30 members of the Baltimore City, Baltimore County, and Harford County Medical Societies. Lengthy testimony was given by many of the attendees at the Reference Committee hearing, expressing their concern for the document containing a list of surgical procedures and diagnoses or symptoms for which inpatient hospital care is denied, issued by the Maryland Foundation for Health Care. It was emphasized that their concern was for the patients' well-being. Some misunderstandings are evidenced by inaccuracies in the Whereas clauses. Those present were advised that whenever a justifiable change was

necessary, this would be considered by the Board of the Foundation. In fact, many objections already have been resolved by this method.

The resolving clauses of Resolution 1A/85 are inappropriate. Notification of the specialty societies was made when the document in question was being prepared. This policy is expected to continue. Therefore, the Reference Committee recommends that Resolution 1A/85 be amended by substituting the following:

Resolved, That the Maryland Foundation for Health Care be urged to establish and publicize a formal channel of communication between specialty societies or individuals who have concerns about any guidelines; quality of medical care should not be sacrificed in the name of cost containment.

The Reference Committee recommends adoption of this resolution as amended.

Resolution 2A/85

Whereas, During the past several months, a committee of the Baltimore City Medical Society has examined the public's perception of physicians and found that the public has a negative perception of the profession;
Whereas, While this negative perception has been generated partly by unfavorable media reports, it has been learned that physicians may be unwittingly furthering this negative perception in their relationships with their patients by exhibiting behavior that is not consonant with the profession's own standards of excellence; and
Whereas, this negative public perception has an adverse effect on the Faculty's ability to achieve some of its purposes as stated in the preamble of the bylaws, i.e.

> "secure the enactment of just laws relating to the practice of medicine and the public health . . . and to enlighten and direct public opinion so that the profession shall become more useful in the prevention of disease, in prolonging and adding comfort to life and in promoting a satisfactory distribution of medical care to the citizens of Maryland."

therefore, be it
Resolved, That a major activity of the Faculty is to promote a positive relationship between the patient and the physician and to that end, be it further
Resolved, That a statewide task force be appointed by the president to develop and direct an effort toward improving and maintaining positive relationships between individual patients and their physicians and to coordinate the activities of local medical societies in this endeavor.

The members present heard the report of the Ad Hoc Committee on the Public Perception of Physicians of the Baltimore City Medical Society, which was attached to this Resolution, introduced by the Baltimore City Medical Society. The report stressed the need to educate physicians on how to relate to their patients and how to raise the consciousness of physicians to the importance of this issue.

While the report and the Resolution call for the establishment of a task force to develop positive relationships between patients and their physicians, it was noted that the Faculty's Public Relations Committee has embarked on an ambitious program with the approval of Council, which could be expanded to address these very issues. It was felt that an additional task force could be extraneous and could work at cross purposes with the Public Relations Committee.

The Reference Committee therefore recommends that Resolution 2A/85 be amended by striking out "a statewide task force be appointed by the president" and inserting "the Public Relations Committee be instructed" so that the Resolution reads as follows:

Resolved, That the Public Relations Committee be instructed to develop and direct an effort toward improving and maintaining positive relationships between individual patients and their physicians and to coordinate the activities of local medical societies in this endeavor.

The Reference Committee recommends adoption of this resolution as amended.

AUBREY C. SMOOT **MD, Chairman, Salisbury**
CHARLES R. CHANEY **MD, Hagerstown**
WILLIAM B. HAGAN **MD, Hyattsville**
GARY L. ROSENBERG **MD, Baltimore**
MARGARET T. SNOW **MD, Silver Spring**

Scientific Activity

Mr. President and Members of the House of Delegates:

Operating in its second year as the Committee on Scientific Activity with expanded responsibilities, the Committee reviewed 22 requests for cosponsorship for CME credits from various societies and agencies such as the Baltimore City Medical Society, Maryland Health Convocation and the Gerontological Association. Among the 22 requests, 18 were approved as submitted, 2 were approved with specific changes within the programs, and 2 were denied cosponsorship by the Committee because of failure to meet the criteria set forth by the ACCME.

The 1984 Semiannual Meeting was held Thursday to Saturday, September 13 to 15, 1984 at the Carousel

Hotel in Ocean City. While the weather was not entirely cooperative, attendance was up from 1980. Nine hours of CME Category I credits were offered for the scientific sessions. Physician attendance was 365, and the total attendance was 508. As in the past, whenever the Semiannual Meeting is held in the state of Maryland, the House of Delegates meets during the meeting. Approximately 100 delegates attended the House of Delegates Meeting.

At this Semiannual Meeting a few exhibitors were invited to set up booths outside of the meeting room and near the registration desk. The proceeds from exhibitors were used to host a Welcoming Wine and Cheese Party for the attendees. A Farewell Dinner Dance was another highlight of the social functions at the meeting. The Auxiliary preceded its business meeting with a fashion show, "Shape Up for Life," in which various Auxilians were the models.

The Annual Meeting (187th) was held this year Thursday to Saturday, April 25 to 27, 1985 at Marriott's Hunt Valley Inn. Some changes were instituted in the overall format of the meeting. For the first time in several years, the Annual Meeting was centered around a theme, "The Challenge of Change." Many of the specialty societies participated with timely topics regarding the changes in medicine. The meeting offered 40 scientific sessions over the three days and was able to offer 19 hours of Category I CME credits.

The highlight of this Annual Meeting was the well-attended Plenary Session on Thursday. "Challenge of Change" was presented by Paul M. Ellwood, Jr., MD, of InterStudy, who is known nationally as "the Father of HMOs." This informative session was attended by approximately 200 physicians and interested parties.

A second Plenary Session was offered on Saturday. It was cosponsored by the Sheppard and Enoch Pratt Hospital and dealt with "Physicians and Their Families" by presenting a panel discussion about physicians and the problems faced by their families. This session also was well attended and received very favorable reports.

In 1984 approximately 35 exhibitors were anxious to exhibit at the Annual Meeting but were unable to because of exhibit space restrictions. In 1985 the Committee decided to use the Valley Room as exhibit space and also the Hunt Room. Using both rooms (combined as the entire Hunt Valley Ballroom) allowed us to accommodate approximately 30 additional booths, thus enhancing the revenue for the Annual Meeting.

Because we used maximum space for exhibits, it was necessary to split the traditional Lunch-and-Learn Session into a Breakfast-and-Learn Session and a Lunch-and-Learn Session. Twelve tables of each were offered in the morning and afternoon on Friday. As in every new session, the Breakfast-and-Learn was not as well attended as hoped. The Committee will review its viability for future meetings.

For a second year a Prayer Luncheon was offered in lieu of the Prayer Breakfast. Reverend Grady F. W. Barbour addressed the topic "Pastoral Care: Profession, Plebeian Career, or Placebo?"

In keeping with the overall theme of the meeting, the Maryland Medical Political Action Committee invited Delegate Larry Young, Chairman, Environmental Matters Committee of the Maryland General Assembly to address its Saturday Luncheon on "Year of the Doctor: Winners or Losers?"

For the second year in a row, the Presidential Banquet and Reception was sold out. Dr. and Mrs. George Malouf hosted this event where 362 attendees enjoyed fine dining, dancing, and the sharp wit of comedian Freddie Roman.

Overall attendance for this year was on par with attendance in the past. Approximately 1,066 physicians attended the meeting; a total of 1,262 reflected physicians and allied health personnel; and an overall attendance of 1,905 during the three days of the meeting.

The 1985 Semiannual Meeting is planned for the Southampton Princess Hotel in Bermuda, Sunday to Sunday, September 1 to 8, 1985. The Committee on Scientific Activity is planning a varied scientific program that will include speakers from the Bermuda Medical Society and physicians from Maryland. An interesting social program is being developed by the Committee and the Auxiliary.

The Committee on Scientific Activity very much appreciates all the assistance given to make this a successful year and wishes to thank the many individuals who gave so willingly of their time and effort.

MORTON I. RAPOPORT **MD, Chairman**
C. EARL HILL **MD**
J. COURTLAND ROBINSON **MD**
JOHN M. KRAGER **MD**
GARY L. ROSENBERG **MD**
JACK ZIMMERMAN **MD**
MRS. MARY E. McGIBBON, **Director of Convention Services**
MS. M'LOU SCHRAM, **Assistant Director of Convention Services**

Secretary

Mr. President and Members of the House of Delegates:

I have been the Secretary of this Faculty since 1977. During these many years, there have been great opportunities to serve the Faculty. Perhaps the most challenging has been this last year, which concludes with

the 1985 meeting. During this last year, your Secretary has been involved with changes affecting the climate of medical practice in our state. In addition to the regular duties of this office, I have met with component societies and the membership on an individual basis, as we comment on the role and the future of medicine in Maryland.

Indeed, the formal responsibilities of this office are discharged efficiently due to the efforts of our fine staff. However, the interactions with the physician members have been most informative and stimulating. Wherever I have travelled there is a sense of concern but also a feeling of cautious optimism. I admire the membership for their continued service to their patients and the dedication to the collective efforts of the Faculty, as together we pursue constructive change during the reformation of the health care delivery system. It is my impression that we are pursuing goals that will insure high quality health care in the future.

As I enter yet another term, the enthusiasm of the Faculty is still without change from that same spirit present in 1978, when I completed my first term in this office.

BERNARD S. KARPERS, JR., MD

Tel-Med

Mr. President and Members of the House of Delegates:

Maryland Tel-Med is part of a nationwide network of 358 telephone information programs throughout the United States, Canada, South America, and Saudi Arabia. Tel-Med, Inc., is a wholly owned subsidiary of the San Bernardino, California, County Medical Society. The Medical and Chirurgical Faculty is the statewide coordinator of eight operating programs in Maryland. The Faculty helps new programs begin operation, reviews and develops scripts for the Maryland Master Library, and in cooperation with Blue Cross and Blue Shield of Maryland assists in funding local programs.

Program Activity

Maryland Tel-Med acquired a new addition in the past year. The Washington County Hospital Association Tel-Med program was officially inaugurated on November 27, 1984. The Washington County Hospital Association was one of the first locations in Maryland to express an interest in Tel-Med, but implementation was delayed due to hospital renovations. Funding for the program was made possible through the Washington County Medical Society and Blue Cross and Blue Shield of Maryland. The program is being operated by volunteer members of the Washington County Hospital Auxiliary, Monday thru Friday, 9 a.m. to 5 p.m.

Idea Exchange

The Peninsula General Hospital Tel-Med program hosted the 4th annual Idea Exchange on November 8, 1984. Representatives from five Maryland Tel-Med programs, the Health Planning Council of the Eastern Shore, Shore Up! Inc., and Med-Chi attended.

The group explored successful promotional techniques being used by several Maryland programs. Gina Grazier, Director of Short Up! Inc., gave a presentation on ways to market Tel-Med effectively and efficiently.

Other ideas discussed at the meeting included volunteer recognition, making Tel-Med tapes in Maryland, and Blue Cross and Blue Shield participation.

Cancer Information Services

Maryland Tel-Med is a participant with the Johns Hopkins University Hospital in a Cancer Information Service (CIS) pilot project. At the present time, many Maryland programs participate in the project that gives Tel-Med callers additional information about the CIS in Maryland. This pilot program is sponsored jointly with the National Cancer Institute. Maryland is the first location to use the Tel-Med service to acquaint the public with CIS.

Services to the Handicapped

Maryland Tel-Med includes 26 scripts from the Access-Info Library. Placement of the scripts is a joint cooperative effort with the office for the Coordination of Services to the Handicapped for the State of Maryland.

Maryland Master Library

In 1984–85 approximately 15 new scripts were accepted into the Maryland Master Library, and 77 were reviewed and reapproved.

Maryland Tel-Med Newsletter

Now in its sixth year of publication, the *Maryland Tel-Med Newsletter* continues to be the primary communication vehicle for the Tel-Med programs throughout the state. All programs are encouraged to submit information and ideas for inclusion in the newsletter. The newsletter is distributed quarterly to hospitals, medical societies, libraries, health departments, and specialty foundations.

Organization

The daily activities of Tel-Med including newsletter publication, script development and revision, and new program development are conducted by Medical and

Chirurgical Faculty Staff, Elza Davis and Nina Casey. Members of the Tel-Med Advisory Committee are responsible for major policy decisions. Members serving in the 1984–85 year were: C. Earl Hill MD, Ruth Mednick, Howard County Department Citizen Service; Elizabeth Duverlie, Maryland Hospital Education Institute; Carmine Valente, Center for Health Education; J. Roy Guyther MD and Edward D. Layne MD.

All contributions to the Maryland Tel-Med program are received by the Medical and Chirurgical Faculty Charitable Fund, Inc., and are tax deductible. Inquiries about the program should be directed to Maryland Tel-Med, 1211 Cathedral Street, Baltimore, MD 21201, or contact Nina Casey at 301-539-0872 or 1(800)-492-1056.

Program Statistics

Location: Anne Arundel General Hospital, Annapolis, Maryland
Date of Implementation: September 12, 1983
Funding Sources: Blue Cross and Blue Shield of Maryland; Annapolis Lions Club; Hospital Auxiliary
Call Volume: 1,115 calls/month
Community Services: Distribution of brochures to hospitals, schools, civic associations, the county health department, and at local health fairs and the Annapolis Spring Festival. Tel-Med placemats in area McDonald's restaurants.
Hours of Operation: 24 hours/day, 7 days/week
Tel-Med Number: 301-263-7755
Contact Person: Lisa Hillman, Public Relations Director, 301-267-1480

• • •

Location: Giant Food, Inc., Landover, Maryland
Date of Implementation: February 15, 1984
Funding Sources: Self-funded
Call Volume: 6,600 calls/month
Community Services: Distribution of brochures in Giant Food stores and to area businesses; advertisements in the newspaper.
Hours of Operation: Monday thru Friday, 9 a.m. to 8 p.m.; Saturday, 9 a.m. to 6 p.m.
Tel-Med Numbers: 341-8000—Washington Area (toll free)
995-8000—Baltimore Area (toll free)
Contact Person: Odonna Mathews, Consumer Affairs Advisor, 301-341-4367

• • •

Location: Memorial Hospital, Easton, Maryland
Date of Implementation: March 26, 1981
Funding Sources: Blue Cross and Blue Shield of Maryland; Upper Shore Aging; Memorial Hospital Junior Auxiliary.
Call Volume: 323 calls/month
Community Services: Part of Community Outreach Education Program. Brochures distributed to public buildings, schools, churches, library, and health department.
Hours of Operation: 7 days/week, 8 a.m. to 11 p.m.
Tel-Med Number: 301-822-9198
Contact Person: Cathy Seyler, Secretary of Health Education Center, 301-822-1000

• • •

Location: Peninsula General Hospital Medical Center, Salisbury, Maryland
Date of Implementation: February 17, 1983
Funding Sources: Wicomico County Medical Society; Blue Cross and Blue Shield of Maryland; the Purnell Foundation; the Perdue Foundation; Mental Health Council.
Call Volume: 146 calls/month
Community Services: Distribution of brochures to various community locations and to patients admitted to the hospital. Articles in the hospital newsletter and advertisements in the local newspaper.
Hours of Operation: Monday thru Friday, 5 to 8 p.m.
Tel-Med Number: 301-546-2857
Contact Person: Virginia Layfield, Director of Development and Community Relations, 301-546-6400.

• • •

Location: Prince George's County Memorial Library, Cheverly, Maryland—SERVICES DISCONTINUED AS OF MAY 30, 1985

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Location: Provident Hospital, Baltimore, Maryland
Date of Implementation: June 7, 1980
Funding Sources: Morris Goldsecker Foundation; United Way; Blue Cross and Blue Shield of Maryland—printed brochures.
Call Volume: 13,483 calls/month
Community Services: Part of health education program. Direct lines into Tel-Med from BWI Airport, Morgan University, and Coppin State College. Placement of brochures in community locations such as senior citizen centers and churches. Service offered to hospital inpatients along with Tel-Hospital.
Hours of Operation: Monday thru Friday, 8 a.m. to 8 p.m.
Tel-Med Number: 301-728-2900
Contact Person: Michele L. McNeill, Director of Community Relations, 301-578-2598.

• • •

Location: St. Mary's County Health Department, Leonardtown, Maryland
Date of Implementation: March 1, 1984
Funding Source: Blue Cross and Blue Shield of Maryland—printed brochures.
Call Volume: 347 calls/month
Community Service: Brochures distributed to public and parochial schools, local business and through the Family Services Program at the Naval Air Station; radio public service announcements; speaking engagements with local businesses and civic and community organizations; immunization project in St. Mary's County Hospital; outdoor magnetic sign advertising.
Hours of Operation: Monday thru Friday, 8:30 a.m. to 4:30 p.m.
Tel-Med Number: 301-862-4170
Contact Person: Mary Novotny, Tel-Med Coordinator, 301-475-8921.

• • •

Location: Washington County Hospital Association, Hagerstown, Maryland
Date of Implementation: November 27, 1984
Funding Sources: Washington County Medical Society and Blue Cross and Blue Shield of Maryland.
Call Volume: 504 calls/month
Community Services: Distribution of brochures through Washington County Tourism Inc., as well as to churches, schools, banks, area businesses, local industries and doctor and dentist offices; radio show interviews; television interview; speaking engagements with local service groups and articles in the local newspaper.
Hours of Operation: Monday thru Friday, 9 a.m. to 5 p.m.
Tel-Med Number: 301-824-8000
Contact Person: Myra Binau, Coordinator of Library Services, 301-824-8801

JAMES E. BELL **MD**
Chairman, Public Relations Committee

Treasurer

Mr. President and Members of the House of Delegates: The financial books and records of the Faculty were audited for the year ending December 31, 1984 by the CPA firm, Wooden and Benson. The audited financial reports reflecting the results of the operations for the year and the financial position of the Faculty at year end will be published in the transactions issue of the *Maryland Medical Journal* in compliance with the By-laws.

The 1985 Budget is presented for your information. Approved by the Council in January, it anticipates a favorable balance of income to be carried over to future years.

JOSE M. YOSUICO **MD**

WOODEN & BENSON
CERTIFIED PUBLIC ACCOUNTANTS

The Medical and Chirurgical Faculty
of the State of Maryland
Baltimore, Maryland

We have examined the balance aheeta of The Medical and Chirurgical Faculty of the State of Maryland as of December 31, 1984 and 1983 and the related atatementa of income, expenditures and transfers, and changes in fund balancea for the yeara then ended. Our examinations were made in accordance with generally accepted auditing atandarda and, accordingly, included such testa of the accounting recorda and auch other auditing procedures as we conaidered necessary in the circumstances.

In our opinion, the financial atatements referred to above present fairly the financial position of The Medical and Chirurgical Faculty of the State of Maryland aa of December 31, 1984 and 1983 and the reaulta of its operationa and the changes in its fund balances for the years then ended, in conformity with generally accepted accounting principles applied on a consiatent basia.

Wooden & Benson

May 8, 1985
Baltimore, Maryland

Exhibit A

The Medical and Chirurgical Faculty of the State of Maryland
Baltimore, Maryland

Balance Sheet

ASSETS	General Fund	Endowment and Special Funds	Plant Fund	Med-Chi Insurance Fund	Total December 31, 1984	Total December 31, 1983
Current						
Cash	$2,789,948	$ 818,630	$ 562,089	$1,244,367	$5,415,034	$4,686,896
Accounts Receivable						
Membership dues, journal advertising	56,280	—	—	—	56,280	50,996
Other funds	233,863	280	—	—	234,143	214,745
Other	69,392	—	—	—	69,392	68,025
The Med-Chi Agency, Inc.	146,479	—	—	—	146,479	70,590
Loans receivable—plant fund	36,842	—	—	—	36,842	36,842
Prepaid expenses	6,497	—	—	—	6,497	15,240
	3,339,301	818,910	562,089	1,244,366	5,964,667	5,143,334
Marketable securities	—	1,420,232	—	—	1,420,232	1,287,089
Investment—The Med-Chi Agency, Inc.	224,632	—	—	—	224,632	200,814
Fixed						
Land, buildings and improvements	—	—	721,448	—	721,448	630,458
Other	113,668	—	373,719	—	487,387	472,504
	113,668	—	1,095,167	—	1,208,835	1,102,962
	$3,677,601	$2,239,142	$1,657,256	$1,244,367	$8,818,366	$7,734,199
LIABILITIES AND FUND BALANCES						
Current						
Accounts Payable						
Trade	$ 2,000	$ 2,115	$ —	$ 225,916	$ 230,031	$ 200,380
Other funds	280	73,077	116,019	44,767	234,143	214,745
The Med-Chi Agency, Inc.	—	—	—	61,035	61,035	50,351
Component societies	568,851	—	—	—	568,851	461,919
Payroll taxes	12,632	—	—	—	12,632	9,681
Accrued expenses	54,724	—	—	—	54,724	60,552
Grants payable	77,508	—	—	—	77,508	77,508
Deferred income	659,883	—	—	—	659,883	594,123
Deferred compensation	—	331,643	—	—	331,643	280,992
Loans payable—general fund	—	—	36,842	—	36,842	36,842
	1,375,878	406,835	152,861	331,718	2,267,292	1,987,093
Fund Balances						
Invested in fixed assets	—	—	1,095,167	—	1,095,167	1,004,177
Designated						
Legal fund	92,245	—	—	—	92,245	92,245
Educational purposes	27,426	—	—	—	27,426	35,336
Other	(970)	—	—	—	(970)	3,220
Undesignated	2,183,022	1,832,307	409,228	912,649	5,337,206	4,612,128
	2,301,723	1,832,307	1,504,395	912,649	6,551,074	5,747,106
	$3,677,601	$2,239,142	$1,657,256	$1,244,367	$8,818,366	$7,734,199

The accompanying notes to financial statements are an integral part of this statement.

Notes to Financial Statements
December 31, 1984

Note 1—Summary of Significant Accounting Policies

The Medical and Chirurgical Faculty of the State of Maryland is a nonprofit organization, tax exempt under Section 501 of the Internal Revenue Code.

Marketable securities are carried at cost. Market values at December 31, 1984 and 1983 were $1,679,940 and $1,688,195, respectively.

The Faculty carries its investment in the 100 percent owned The Med-Chi Agency, Inc. at equity. The net assets of the corporation as of December 31, 1984 and 1983 were as follows:

	1984	1983
Current assets	$446,928	$292,798
Fixed assets—net	5,686	11,643
	452,614	304,441
Current liabilities	227,982	103,627
	224,632	$200,814

Fixed assets of the plant fund, other than personal property are recorded at cost. Portraits were appraised as of December 31, 1963 at $65,000, an increase of $51,000 over prior years. All other personal property was appraised as of December 31, 1949. Depreciation on fixed assets is not provided. A schedule of fixed assets follows:

Exhibit B

Statement of Income, Expenditures and Transfers
General Fund (Undesignated)

	For Years Ended December 31, 1984	December 31, 1983
Income		
Dues	$1,146,683	$1,149,160
Rents and services	10,046	13,671
Meetings	58,440	54,329
Journal advertising and subscriptions	124,318	107,148
Interest	272,370	197,073
Miscellaneous	118,479	110,004
Equity interest in The Med-Chi Agency, Inc.	98,818	66,749
	1,829,154	1,698,134
Expenditures		
Operating expenses	1,477,336	1,378,741
Excess of income over expenditures	351,818	319,393
Transfers—Endowment and Special Funds		
From consolidated fund income	6,750	8,053
From special funds	9,308	12,432
To special funds—deferred compensation	(21,608)	(21,608)
	(5,550)	(1,123)
Excess of income and transfers over expenditures	$ 346,268	$ 318,270

The accompanying notes to financial statements are an integral part of this statement.

Exhibit C

Statement of Income and Expenditures
Med-Chi Insurance Fund

	For Years Ended December 31, 1984	December 31, 1983
Income		
Administrative fees	$ 46,792	$ 40,813
Interest	221,738	93,805
	268,530	134,618
Expenditures		
Administrative services	24,771	24,159
Postage, printing, and supplies	697	—
Rent	1,044	1,044
Telephone	480	480
Professional fees	990	900
Contributions	20,000	28,200
	47,982	54,783
Excess of income over expenditures	$220,548	$ 79,835

The accompanying notes to financial statements are an integral part of this statement.

Real Estate	**1984**	**1983**
1209–1215 Cathedral Street		
Land and building	$ 110,636	$ 110,636
Improvements	347,014	331,525
1205–1207 Cathedral Street		
1204 Maryland Avenue		
Land and buildings	100,862	25,361
Improvements	162,936	162,936
	721,448	630,458
Other		
Library books, journals	231,370	231,370
Office and library—fixtures, antiques and museum pieces	77,349	77,349
Portraits—appraised value	65,000	65,000
	373,719	373,719
	$1,095,167	$1,004,177

Fixed assets of the general fund are recorded at cost and depreciated using the straight-line method over their estimated useful lives for assets acquired prior to 1981 and using the accelerated cost recovery system for assets acquired after 1980.

	December 31, 1984	December 31, 1983	Life in Years
Auto equipment	$ 9,796	$ 9,796	4
Office equipment	236,815	176,001	5–10
Total cost	246,611	185,797	
Less—accumulated depreciation	132,943	87,012	
	$113,668	$ 98,785	

Provision for depreciation charged to operations for the years ended December 31, 1984 and 1983 was $45,931 and $31,930, respectively.

Note 2—Pension Plan

The Faculty has a noncontributory pension plan covering substantially all its employees. Pension contributions for the current year and prior year were $54,724 and $55,125, respectively, which includes amortization of prior service cost over 20 years. The Faculty's policy is to fund pension costs accrued. Actuarial determined pension costs are funded on an annual basis by the Frozen Initial Liability method with initial accrued liabilities computed under the Entry Age Normal Cost method. A comparison of accumulated plan benefits and plan net assets for the Faculty is presented below:

Actuarial Present Value of Accumulated Plan Benefits	**1984**	**1983**
Vested	$726,453	$480,399
Nonvested	92,359	23,037
	$818,812	$503,436
Net assets available for benefits	$924,731	$867,257

The assumed rate of return used in determining the actuarial present value of accumulated plan benefits was 6.5 percent for both 1984 and 1983. The fund's assets as of April 1, 1984 and April 1, 1983 exceeded the vested benefits by $198,278 and $386,858, respectively.

Note 3—Related Parties

The Medical and Chirurgical Faculty of the State of Maryland owns the stock of The Med-Chi Agency, Inc. The Faculty leases office space to the Agency under a month-to-month lease. Lease payments from the Agency were $9,396 for 1984 and 1983. Additionally, the Faculty performed certain management and accounting services for the Agency; income for these services was $56,000 in 1984 and 1983.

Note 4—Contingency

The Faculty has entered into a deferred compensation agreement with the Executive Director of the Faculty. The agreement provides for compensation to be accumulated in a reserve account and paid upon the termination of employment, conversion from full to part-time employee status, or partial or total incapacitation.

Statement of Changes in Fund Balances
For Year Ended December 31, 1984

	Balance January 1, 1984	Additions: Excess of Income Over Expenditures and Transfers	Additions: Investment Income	Additions: Interest on Savings Accounts	Additions: Plant Fund Assessments of Members	Additions: Other Income and Contributions Received	Additions: Gain on Sale of Securities	Additions: Gain on Sale of Land	Deductions: Transfers In (Out)	Deductions: Expenditures	Balance December 31, 1984
General Fund Designated	$ 130,801	$ —	$ —	$ —	$ —	32,608	$ —	$ —	$ —	$ 44,708	$ 118,701
Undesignated	1,836,754	346,268	—	—	—	—	—	—	—	—	2,183,022
Endowment and Special Funds	1,668,773	—	108,293	19,666	—	250	86,927	—	(6,750)	44,852	1,832,307
Plant Fund	1,418,677	—	—	59,406	25,540	772	—	—	—	—	1,504,395
Med-Chi Insurance Fund	692,101	220,548	—	—	—	—	—	—	—	—	912,649
	$5,747,106	$ 566,816	$ 108,293	$ 79,072	$ 25,540	$ 33,630	$ 86,927	—	$ (6,750)	$ 89,560	$6,551,074

For Year Ended December 31, 1983

	Balance January 1, 1983	Additions: Excess of Income Over Expenditures and Transfers	Additions: Investment Income	Additions: Interest on Savings Accounts	Additions: Plant Fund Assessments of Members	Additions: Other Income and Contributions Received	Additions: Loss on Sale of Securities	Additions: Gain on Sale of Land	Deductions: Transfers In (Out)	Deductions: Expenditures	Balance December 31, 1983
General Fund Designated	$ 148,038	$ —	$ —	$ —	$ —	$ 26,820	$ —	$ —	$ —	$ 44,057	$ 130,801
Undesignated	1,518,484	318,270	—	—	—	—	—	—	—	—	1,836,754
Endowment and Special Funds	1,689,499	—	97,774	18,904	—	1,089	60,303	—	(177,218)	21,578	1,668,773
Plant Fund	996,800	—	—	18,411	22,272	100	—	225,239	156,733	878	1,418,677
Med-Chi Insurance Fund	612,266	79,835	—	—	—	—	—	—	—	—	692,101
	$4,965,087	$ 398,105	$ 97,774	$ 37,315	$ 22,272	$ 28,009	$ 60,303	$ 225,239	$ (20,485)	$ 66,513	$5,747,106

The accompanying notes to financial statements are an integral part of this statement.

Proposed Budget 1985

Estimated Income

	Budget 1984	Projected Actual thru Dec. 31, 1984	Budget 1985
Membership Dues	$1,135,000	$1,146,685	$1,160,000
Investment Income			
Restricted Fund Earnings	15,000	16,000	16,000
Short Term Interest	150,000	230,000	180,000
Medical Journal	100,000	124,000	120,000
Annual & Semiannual Meetings	60,000	57,515	60,000
Administrative Services	80,000	80,000	80,000
Other Income	30,000	27,500	30,000
Total	$1,570,000	$1,681,700	$1,646,000

Estimated Expenditures

	Budget 1984	Projected Actual Thru Dec 1984	Budget 1985
Auditing	$ 6,600	$ 6,900	$ 6,900
Legal	5,000	5,000	5,000
Contributions	1,000	400	1,000
Gas, Electricity, Water	25,000	25,884	28,000
Telephone & Telegraph	30,000	25,768	30,000
Postage	40,000	39,000	44,000
Household & Janitorial	8,000	8,994	10,000
Property Maintenance	15,000	10,105	15,000
Insurance	12,000	12,000	14,000
Special Equipment Services	3,000	1,500	2,000
New Equipment	15,000	3,000	15,000
Equipment Maintenance	4,000	1,500	2,000
Stationary & Supplies	15,000	12,390	15,000
Salaries	711,000	704,273	782,000
Social Security	47,000	44,120	52,000
Unemployment Compensation	8,000	7,100	8,000
Employee's Insurance Progam	50,000	52,055	55,000
Employees Pension	66,000	64,000	66,000
Supplementary Hours	4,000	4,000	4,000
Travel	90,000	88,000	85,000
Printing	25,000	22,810	25,000
Data Processing	15,000	13,161	15,000
Governmental Relations	20,000	22,915	25,000
Library	20,000	20,000	20,000
Journal Expense	135,000	132,000	135,000
Annual & Semiannual Meetings	100,000	99,588	100,000
Presidential Fund	10,000	10,000	10,000
Auxiliary	1,000	1,000	1,000
Miscellaneous Expense	25,000	20,242	25,000
Depreciation	40,000	40,000	40,000
Total	$1,546,600	$1,497,711	$1,635,900

1985 Budget Notes

A. Contributions:	Reflects a reserve for possible requests during the year.
B. Travel:	Includes attendance at following meetings: Professional Convention Management Association, 1st week in January, 1985 (two staff members). Regional Legislative Conference, January, two staff members. National Medical Leadership Conference, Chicago; President, President-elect, Council Chairman, two staff members, February 14–16. Chief Executive Officers, State Medical Association, Orlando, Florida & Colorado Springs, Colorado. Six Delegates, Six Alternates, President, President-elect and staff to attend. 1. AMA Annual Meeting, Chicago–June 2. AMA Interim Meeting—DC—December Medical Society Executive Conference, in conjunction with above, three staff members. American Society of Association Executives, Annual Meeting or similar education activity. AAMSE (American Association of Medical Society Executives) (two staff members). Travel throughout the state for various component society meetings, other business and activities, as well as out of state Regional and National Sessions as determined on an individual basis.
C. Printing:	Includes the publication cost of the membership directory.
D. Governmental Relations:	Includes nurses' salaries and supplies for First Aid Room, publications printing and mailing costs, and travel.
E. Library:	Includes Memberships, Travel, Supplies, Equipment, Xeroxing, Postage, and Miscellaneous Library expenditures. Library salaries are in the salary account. Journal subscriptions, books, binding, etc. are purchased by designated funds and are not included in this item.
F. Annual & Semiannual Meeting Expenses:	New expenditure items of over $5,000 for these meetings (exclusive of pass-through items) to be approved by Executive Committee or Council. Arrangements and costs for Presidential Banquet and other social events, to be cleared by Executive Committee.

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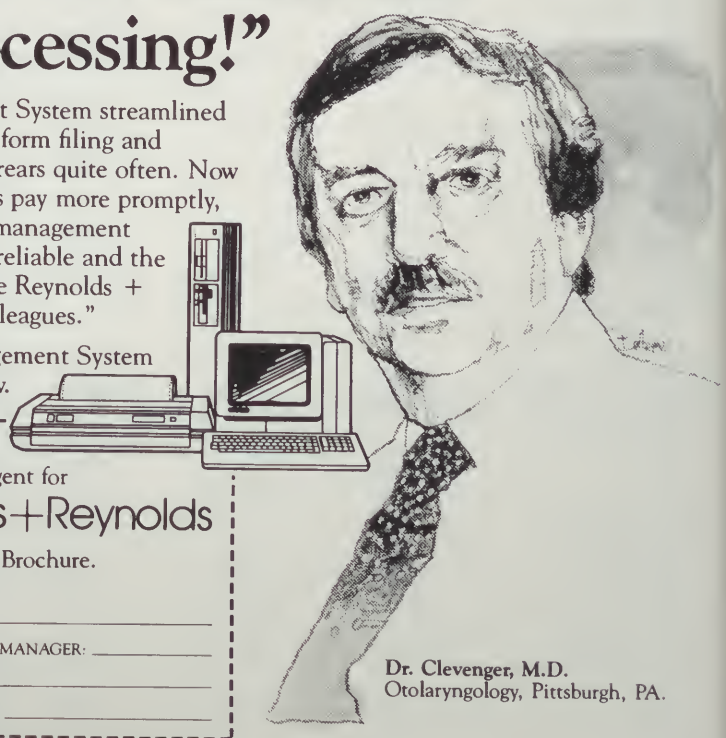
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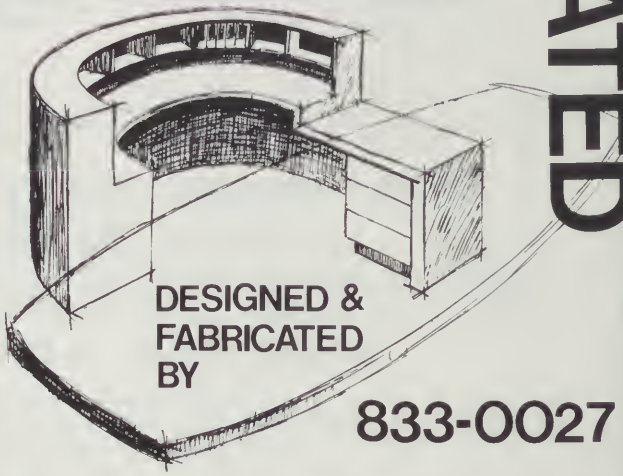
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Sep 9 Ethical Issues in the Healthcare of the Emancipated Minor. Baltimore Plaza Hotel. Fee: $25 6 AMA Cat I credits.

Sep 17 Current Concepts in Ophthalmology: 7th Annual Clinical Conference. Hyatt Regency, Baltimore. Fee: $50; 6 AMA Cat I credits.

Sep 26–27 CO_2 Lasers for Otolaryngologists and Allied Specialties. UMAB Campus. Limited to 20 physicians. Fee: $675; 12.75 AMA Cat I credits.

Nov 13 DSM III - Anxiety. International Hotel at BWI. Fee: $40; 6 AMA Cat I credits.

Nov 21–23 Symposium on Obstetrics and Gynecology: An Up-to-Date Postgraduate Course. Baltimore Plaza Hotel. Fee: $150; 13 AMA Cat I credits.

Nov 23 Higher Cortical Function and Dysfunction in the Elderly. Hyatt Regency, Baltimore. Fee: TBA; 6 AMA Cat I credits.

Oct thru May-Visiting Practitioner Preceptorship Program. Acceptance on approval of Department. Hour-for-hour AMA Cat I credit.

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Miscellaneous Meetings

Aug 23–24 Training for Health: Prevention and Treatment of Common Athletic Injuries, sponsored by Trieber Associates, Inc. and Southern Medical Association. Fee: $350. Info: Trieber Associates, Inc., 9407 Jodale Road, Randallstown, MD 21133 (301-655-5062).

Sep 20 Eastern Shore Oncology Conference, sponsored by the American Cancer Society and Peninsula General Hospital Medical Center, 5 to 9 p.m., Wicomico Youth and Civic Center, Salisbury. 4 Cat I credits; info: 301-749-1624.

Sep 21 Fall Meeting of the American College of Surgeons, Uniformed Service University of Health Sciences, 4301 Jones Ridge Road, Bethesda, MD 20814. Begins at 9 a.m.; 3 CME credits. Info: William G. Armiger MD (301-646-3226).

Sep 21 Prescription for the Planet in the Nuclear Age, sponsored by the Delaware Academy of Medicine and Physicians for Social Responsibility, Delaware Chapter: Grand Opera House, Wilmington: 7 Cat I credits of Physician's Recognition Award of the AMA. Info: Physicians for Social Responsibility/Delaware, P.O. Box 7588, Newark, DE 19714 (302-454-3600).

Sep 27 Clinical Problems of the Aged presented by the Department of Medical Education, Suburban Hospital, 8600 Old Georgetown Rd., Bethesda, MD 20814. Info: 301-530-3869.

Oct 4 Selected Topics in Pediatrics, sponsored by Eastern Virginia Medical School, Children's Hospital of the King's Daughters, Norfolk, VA. Info: J. E. Shelton MD, Children's Hospital of the King's Daughters, 800 West Olney Road, Norfolk, VA 23507 (804-628-3798).

Oct 5 Advances in Human Genetics and Reproduction, organized by the Genetics & IVF Institute and the Fairfax Hospital. Crystal Gateway Marriott, Arlington, VA. CME Cat I credit; info: 703-698-3101.

Oct 16 Up-Date in Therapeutics, Cross Keys Inn, Baltimore, sponsored by the Department of Medicine and the Department of Medical Education, Bon Secours Hospital. 7 CME Cat I credits. Info: 301-362-3027.

Oct 18 Using Your Computer to Keep Current, presented by the Department of Medical Education, Suburban Hospital, 8600 Old Georgetown Rd., Bethesda, MD 20814. Info: 301-530-3869.

Nov 1–2 Training for Health: Prevention and Treatment of Common Athletic Injuries, Philadelphia, PA, sponsored by Trieber Assoc., Inc., and Southern Medical Assoc. Fee $350 (including hotel); info: Trieber Assoc., Inc., 9407 Jodale Rd., Randallstown, MD 21113 (301-655-5062).

Nov 5–8 Fall Meeting American Academy of Clinical Anesthesiologists, Atlantic City, New Jersey, Resorts International Hotel. Info: AACA, POB 11691, Knoxville, TN 37939 (615-588-6279).

Nov 14–15 Pediatric Head Injury: Innovative Approaches to Rehabilitation, presented by the Rehabilitation Institute of Pittsburgh. Info: The Rehabilitation Institute of Pittsburgh, 6301 Northumberland St., Pittsburgh, PA 15217 (412-521-9000, ext. 325 or 343).

Nov 20–22 8th National Trauma Symposium-Making a Difference, Sheraton Inner Harbor, Baltimore. Complete programs to be mailed in August.

• • •

Taylor Manor Hospital CME Lectures

All lectures at 3 p.m. in the Psychiatric Center at Taylor Manor Hospital, Ellicott City, MD unless otherwise indicated. Info: Taylor Manor Hospital, College Ave., Ellicott City, MD 21043 (301-465-3322).

Sep 11 Forensic Psychology Update; Current Critical Issues in Mental Health Law

Oct 16 Diagnostic Confusion Over Depressive Disorder in Adolescents

Nov 13 Family Therapy for Behavior Disordered Adolescents.

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Activities for 1984–85. Info: Office of Continuing Education, 720 Rutland Ave., Turner Auditorium, Baltimore, MD 21205 (301-955-5880).

Sep 5–6 Pediatrics for the Practitioner Update, 85, sponsored by the Department of Pediatrics and the Division of General Pediatrics. Fee: $150 physicians, $100 nurse/practitioners, $75 interns. Info: J. Ryan, Program Coordinator.

Sep 6–7 Fourteenth Annual Diagnostic Ultrasound in Obstetrics and Gynecology at the Baltimore Plaza Hotel. Fee: $240 physicians, $165 sonographers/technicians; 12 AMA Cat I credits.

Sep 20–21 Rheumatology Update, 1985 sponsored by The Johns Hopkins University School of Medicine, The Maryland Society for Rheumatic Diseases, Maryland Lupus Foundation, and The Arthritis Foundation, Maryland Chapter. Fee: $100 physicians, $50 arthritis health professions, $50 nurses; 1 AMA Cat I credit.

Oct 3–4 The Health Care Provider: Infectious and Reproductive Hazards, Medical, Legal, and Ethical Issues, at the School of Hygiene and Public Health, Department of Environmental Health Sciences, Baltimore. Info: 301-955-2609.

Oct 3–5 Eleventh Annual Topics in Gastroenterology and Liver Disease. Fee: $300 physicians, $150 Residents and Fellows; application has been made for 20 AMA Cat I credits.

Oct 18–19 Topics in Allergy and Otolaryngology, The Asthma and Allergy Foundation, Maryland Chapter, cosponsor. Fee: $200; 12.5 CME credits. Info: J. Ryan 301-955-6046.

Oct 21–25 Twenty-seventh Annual Emil Novak Memorial Course: Gynecology, Gynecological Pathology, and High-Risk Obstetrics. Fee: $550 regular, $400 residents; 47 3/4 AMA Cat I credits.

Nov 16 Seminar on Toxicologic Emergencies, sponsored by the Department of Emergency Medicine and Maryland Poison Control Center. Fee: $55; 6 AMA, ACEP and other appropriate credit pending.

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The Department of Radiology and Radiological Science, offers several courses in abdominal and obstetrical ultrasound: courses scheduled Jan 14 to Dec 6, 1985. Info: Joan Mosmiller, Department of Radiology (301-955-8450).

Basic Practicum Sep 23–27. Fee: $460; 40 AMA Cat I credits.

Advanced Practicum Dec 2–6. Fee $460; 40 AMA Cat I credits.

Visiting Physicians offered weekly throughout the year for experience in the lab and participation in reading sessions. By appointment. Fee: $460; 40 AMA Cat I credits.

Advanced Obstetrics and Gynecology course designed for obstetricians who have been using real time ultrasound. Nov 18–20. Fee: $325; 24 AMA Cat I credits.

Diagnostic Ultrasound in Obstetrics and Gynecology course given annually attracts worlds leading experts in the field of obstetrical and gynecology ultrasound. Sep 12–13, 1985; 16 AMA Cat I credits.

The Johns Hopkins Medical Grand Rounds. Accredited audiovisual subscription program for the practicing physician. 40 AMA Cat I credits/year. Write to the Johns Hopkins University School of Medicine, Office of Continuing Education, 720 Rutland Ave., Baltimore, MD 21205 (301-955-3988).

PHYSICIAN PLACEMENT SERVICE

The Medical and Chirurgical Faculty of the State of Maryland maintains a Placement Service for the convenience of Maryland physicians, hospitals and communities in search of candidates for positions available in our state. A detailed description of such opportunities should be forwarded to the Physician Placement Service, 1211 Cathedral St., Baltimore, MD 21201; telephone 1-301-539-0872.

Physicians wishing to locate in Maryland are invited to submit a resumé to be kept on file with the Physician Placement Service. Candidates are requested to inform the Faculty when they are no longer available for consideration for opportunities which might be available in Maryland.

Journal announcements on the Classified Advertising page for Physician Placement Service are charged at the regular Classified Advertising rate.

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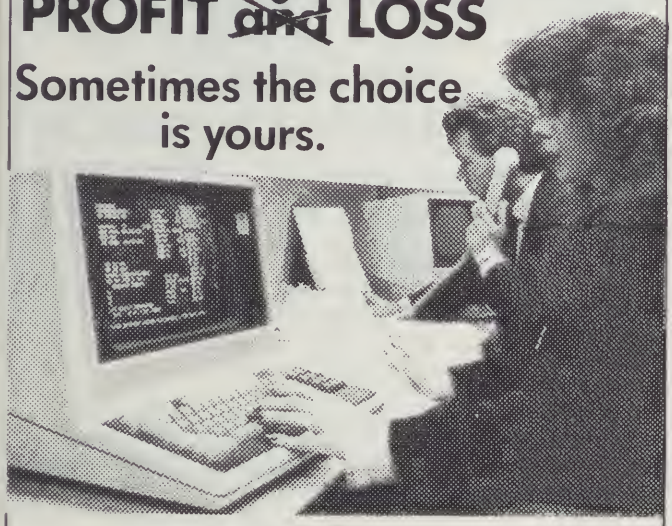
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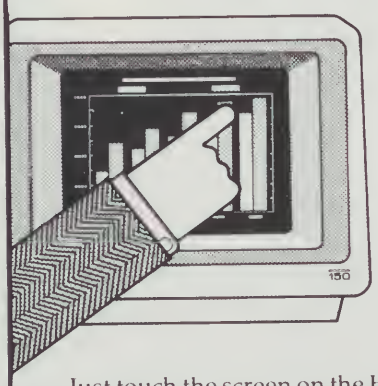
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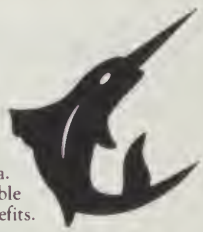
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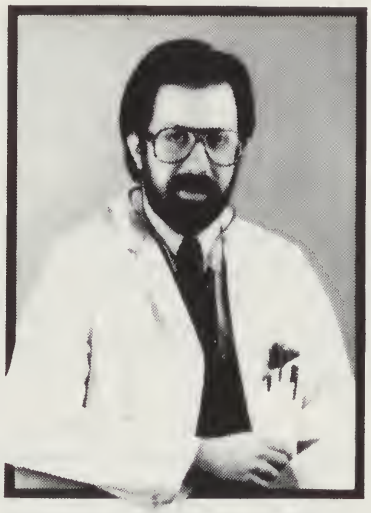
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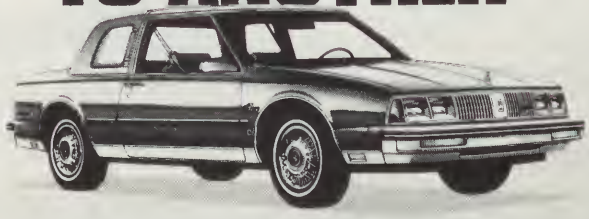
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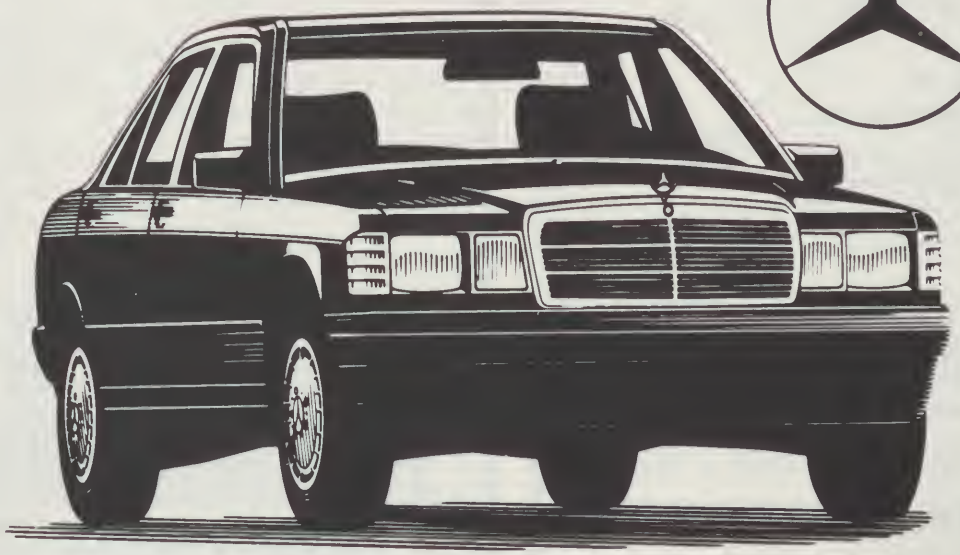
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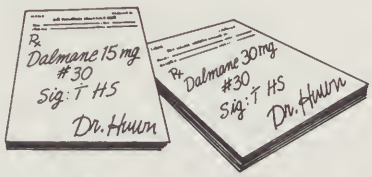
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Indications: Effective in all types of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings and/or early morning awakening; in patients with recurring insomnia or poor sleeping habits; in acute or chronic medical situations requiring restful sleep. Objective sleep laboratory data have shown effectiveness for at least 28 consecutive nights of administration. Since insomnia is often transient and intermittent, prolonged administration is generally not necessary or recommended. Repeated therapy should only be undertaken with appropriate patient evaluation.

Contraindications: Known hypersensitivity to flurazepam HCl; pregnancy. Benzodiazepines may cause fetal damage when administered during pregnancy. Several studies suggest an increased risk of congenital malformations associated with benzodiazepine use during the first trimester. Warn patients of the potential risks to the fetus should the possibility of becoming pregnant exist while receiving flurazepam. Instruct patient to discontinue drug prior to becoming pregnant. Consider the possibility of pregnancy prior to instituting therapy.

Warnings: Caution patients about possible combined effects with alcohol and other CNS depressants. An additive effect may occur if alcohol is consumed the day following use for nighttime sedation. This potential may exist for several days following discontinuation. Caution against hazardous occupations requiring complete mental alertness (*e.g.*, operating machinery, driving). Potential impairment of performance of such activities may occur the day following ingestion. Not recommended for use in persons under 15 years of age. Though physical and psychological dependence have not been reported an recommended doses, abrupt discontinuation should be avoided with gradual tapering of dosage for those patients on medication for a prolonged period of time. Use caution in administering to addiction-prone individuals or those who might increase dosage.

Precautions: In elderly and debilitated patients, it is recommended that the dosage be limited to 15 mg to reduce risk of oversedation, dizziness, confusion and/or ataxia. Consider potential additive effects with other hypnotics or CNS depressants. Employ usual precautions in severely depressed patients, or in those with latent depression or suicidal tendencies, or in those with impaired renal or hepatic function.

Adverse Reactions: Dizziness, drowsiness, lightheadedness, staggering, ataxia and falling have occurred, particularly in elderly or debilitated patients. Severe sedation, lethargy, disorientation and coma, probably indicative of drug intolerance or overdosage, have been reported. Also reported: headache, heartburn, upset stomach, nausea, vomiting, diarrhea, constipation, GI pain, nervousness, talkativeness, apprehension, irritability, weakness, palpitations, chest pains, body and joint pains and GU complaints. There have also been rare occurrences of leukopenia, granulocytopenia, sweating, flushes, difficulty in focusing, blurred vision, burning eyes, faintness, hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anorexia, euphoria, depression, slurred speech, confusion, restlessness, hallucinations, and elevated SGOT, SGPT, total and direct bilirubins, and alkaline phosphatase, and paradoxical reactions, *e.g.*, excitement, stimulation and hyperactivity.

Dosage: Individualize for maximum beneficial effect. *Adults*: 30 mg usual dosage; 15 mg may suffice in some patients. *Elderly or debilitated patients*: 15 mg recommended initially until response is determined.

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Medicolegal Hotline 912
Information for Authors 914
Doctors Take Note 925
Classified Ads 929
Advertisers' Index 931

ARTICLES

Osteoarthritis XI: Lumbar Spondylosis—Ira T. Fine MD 879

Prenatal Diagnosis of 45, X/46, XY—James L. Waurin MD, John E. Adams MD, and Theodore A. Baramki MD 883

Recent Advances in the Early Diagnosis of Osteoporosis: A Review—Robert D. Katz MD 889

Smoking: The Number One Health Problem—Edward N. Brandt, Jr., MD 897

Supporting Maryland Physicians: The Med-Chi Staff—Eve Lehman 900

DEPARTMENTS

Your Medical Faculty at Work 851

Disease Control and Epidemiology Newsletter 853

Today's Psychiatry 859

Maryland Oncology Newsletter 860

The Library Page 863

HBP Commentary 869

One Minute with Diabetes 873

Insurance Monitor 874

Inside Med-Chi 877

Discipline Commission Action 917

Robert D. Katz MD refutes myths about osteoporosis and describes a major recent advance in its diagnosis in an article beginning on page 889. *Cover design*: John D. Benson, Illustrator.

The views in this publication are those of the authors and do not necessarily reflect the opinion of the Medical and Chirurgical Faculty of the State of Maryland.



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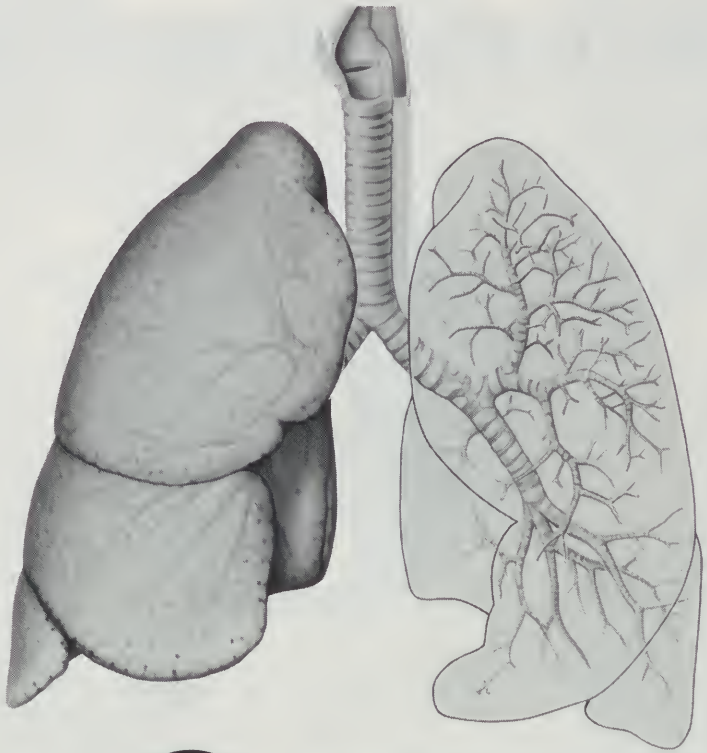
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Brief Summary. Consult the package literature for prescribing information.

Indications and Usage: Ceclor* (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms.

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae), Haemophilus influenzae,* and *S. pyogenes* (group A beta-hemolytic streptococci)

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor

Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Precautions: *General Precautions* — If an allergic reaction to Ceclor* (cefaclor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy — *Pregnancy Category B* — Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor* (cefaclor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers — Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Ceclor is administered to a nursing woman.

Usage in Children — Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below.

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbilliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic — Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic — Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal — Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[061782R]

Note: Ceclor* (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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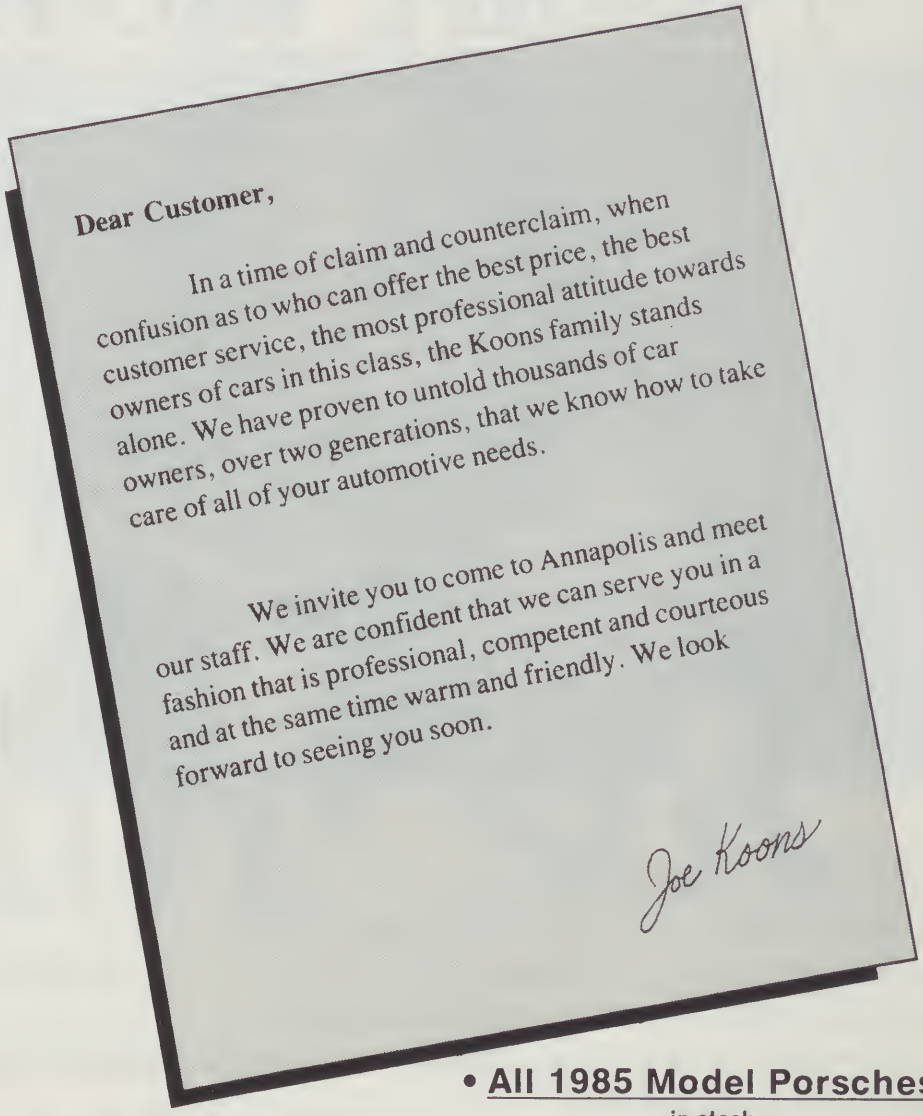
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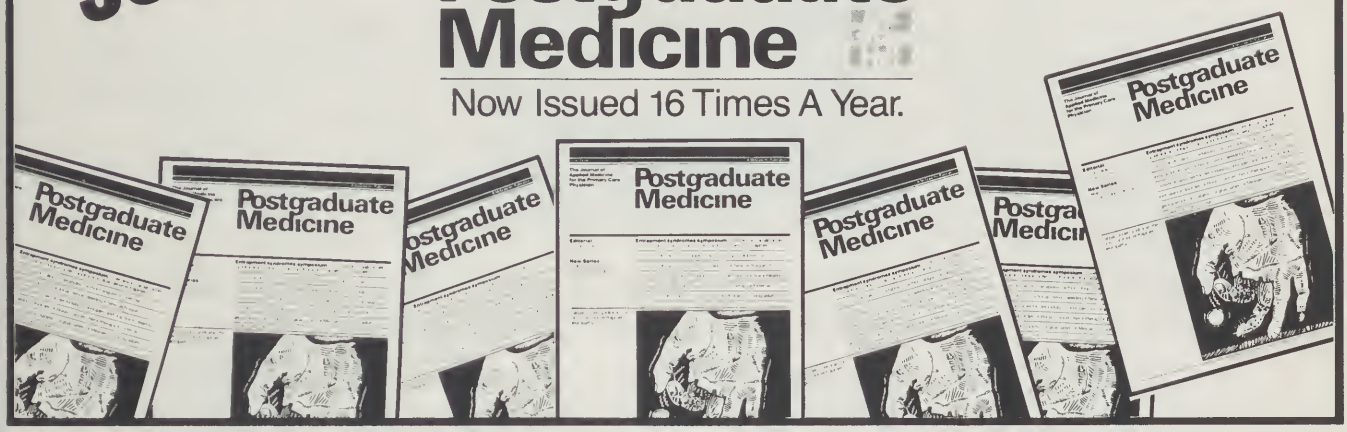
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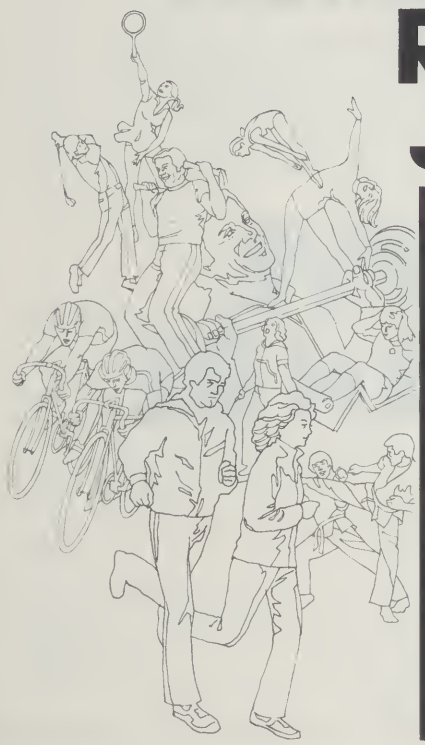
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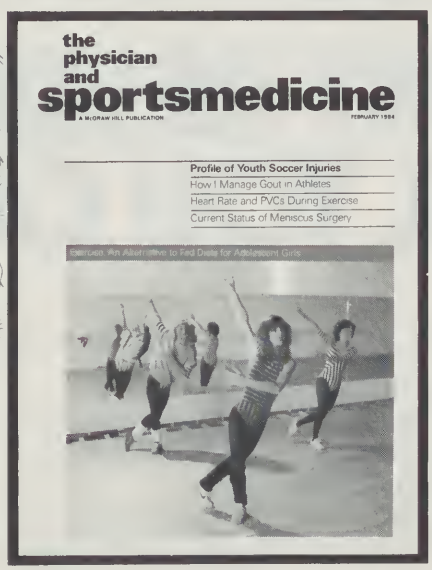
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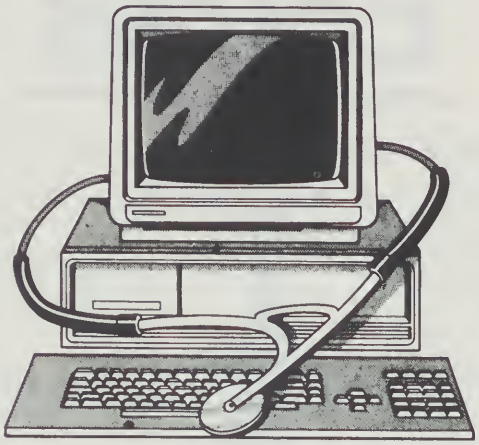
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Executive Director's Newsletter

September 1985

PROFESSIONAL LIABILITY SEMINAR

Delegate Larry Young, (D, 39th District, Baltimore City) is cooperatively sponsoring an in-depth study of the Professional Liability problem. The public meeting is set for Monday, November 4, from 8:30 a.m. to 5 p.m. in Baltimore City (locations to be announced).

Registration fee is $35 per person. Called a Teach-In on Professional Liability, it will explore in detail all aspects as seen from different viewpoints: insurance organizations, trial and defense attorneys, physicians, and consumer groups. For further details, call the Faculty office, 800-492-1056 or 301-539-0872.

OTHER AREAS OF PROFESSIONAL LIABILITY

The Montgomery County Medical Society held an open forum for its members and General Assembly Delegation in mid-August to air the views of physicians to their legislators. Over 200 physicians showed up, along with most of the Senators and Delegates from that area of the state.

A group of physicians calling themselves Marylanders for Malpractice Liability Reform has organized to assist in tort reform efforts during the 1986 General Assembly session. The five physician organizers have financed the initial costs of this operation.

Ms. Frances Tompkins, RN, former Director of Nursing at Union Memorial Hospital, has been employed as the Executive Officer to handle administrative details.

This group has the endorsement of the Faculty in its endeavors and will work in close cooperation with Faculty officials, committees, and groups. An organizational meeting is set for Thursday, September 19, 1985, at 7:30 p.m. at Gilman School.

The Governor has named a task force to look into liability insurance problems of local governments, day care centers, and other groups having this difficulty. Lt. Governor Joseph Curran, Jr., heads this task force, which is coordinating its activities with the Health Professionals Liability Task Force.

FOREIGN MEDICAL GRADUATES

The AMA House of Delegates has adopted a position dealing with graduates of medical schools from countries other than the U.S. and Canada. This position is

> Resolved, It is the position of the AMA that the quality of a physician's medical education is an appropriate consideration in the recruitment and licensure of physicians and that discrimination against physicians on the basis of the country in which they completed their medical education is inappropriate.

THE MEDICAL FAMILY -- TO YOUR HEALTH

The Committee on Physician Rehabilitation has scheduled a seminar for Thursday, November 7, 1985, at the Faculty Building. The all-day meeting will commence at 9 a.m.

The seminar will focus on subjects such as stress of a malpractice suit, strengths and weaknesses of the physician's family, the impaired physician, and the physician's marriage.

Registration fee is $25/person or $40/couple, including lunch.

RESIGNATION FROM MEDICARE PROGRAM

Physicians who no longer wish to participate in the Medicare program must submit their resignation in writing by October 1, 1985. Letters may be submitted immediately; however, resignation will not be effective until October 1, 1985.

RESOLUTIONS

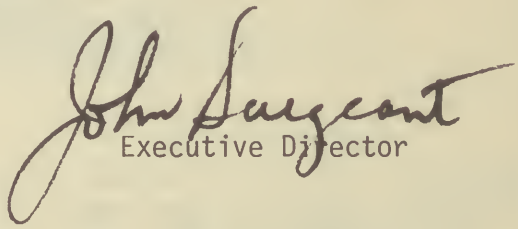
No resolutions were received in the Faculty office by Friday, August 2, 1985, the deadline for receipt of resolutions. Therefore, there will be no Reference Committee meeting and no report presented to the House of Delegates at the Semiannual Meeting on September 28.

MARKETING TECHNIQUES SEMINAR

The Faculty is planning two one-day seminars on "Marketing Techniques for Successful Practice" to be held Tuesday and Wednesday, November 5-6, 1985. One seminar will be held in the Baltimore City area and the other is planned tentatively for the Prince George's/Montgomery County area. Watch your mail for these upcoming seminars.

LIABILITY INSURANCE INCREASES

A number of physicians have indicated their intention to discontinue the practice of medicine because the escalating cost of professional liability insurance makes it impossible to continue. It would be extremely helpful in our future legislative efforts to have documentation of these incidents. If you or someone you know has left practice or is planning to do so, please contact me at the Faculty office, 301-539-0872 or 800-492-1056. Let me know your specialty, number of years in practice, location of practice by county, amount of professional liability premium - current billing and amount of premium for immediate past year.



Executive Director

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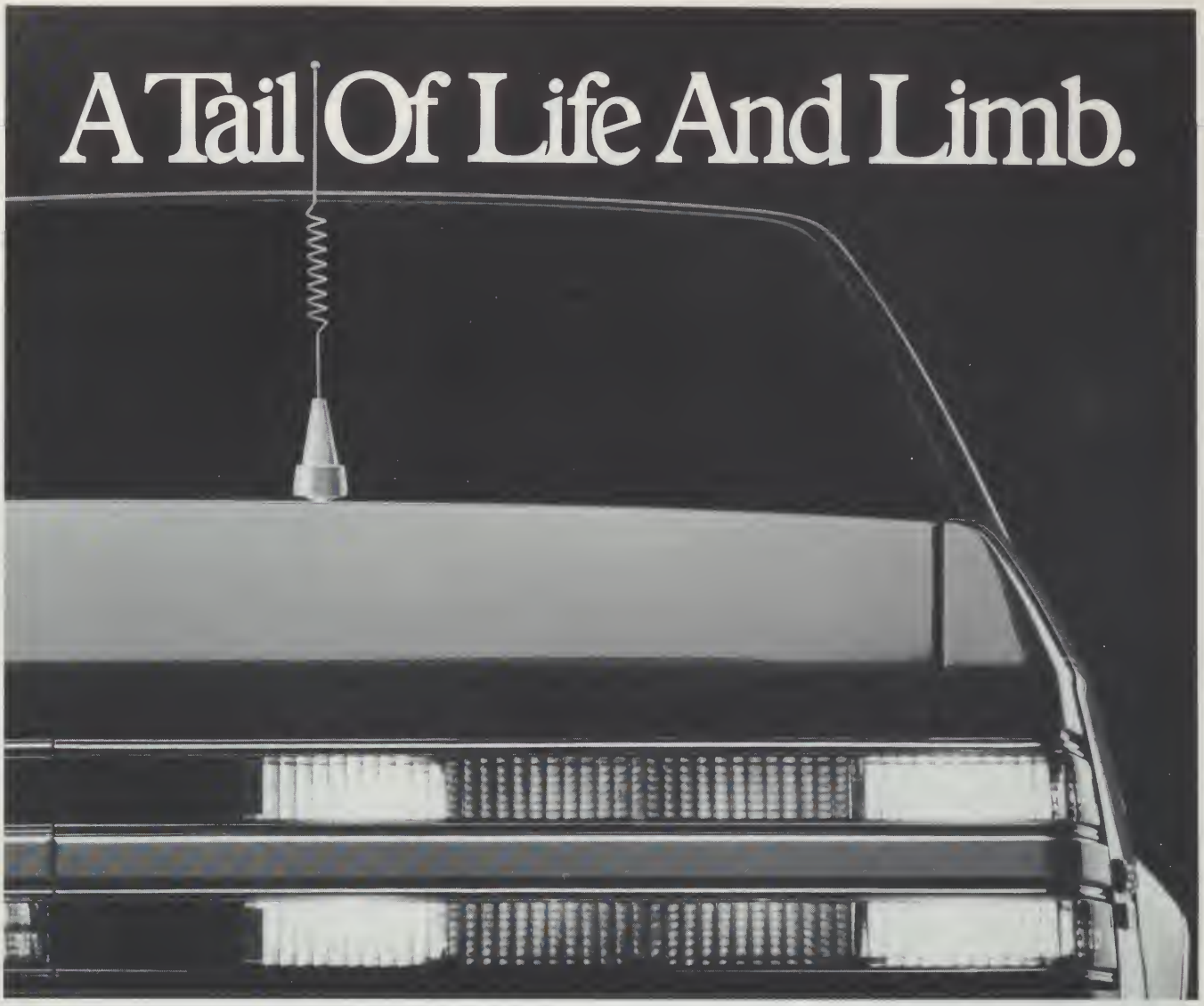
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Your Medical Faculty at Work

The Council again took action to protect patients' interests when it agreed to challenge the recent *Coe* Consent Decree, which gives the right to outside individuals to be present during treatment of patients in state psychiatric facilities. Council stated support of the clinical staffs of state psychiatric facilities and deemed it essential that a nonadversarial treatment environment be maintained. To attempt clarification of this issue, Council representatives are seeking a meeting with the Secretary of the Department of Health and Mental Hygiene.

Council authorized legal action, if necessary, to challenge certain laboratory proficiency testing programs being required of all physicians who perform laboratory services in their offices. The Faculty has protested the proposed regulations in this regard, but such protestations have not been heeded. Council concurred that this type of regulation will not only increase costs to the patient but also present other inconveniences.

Legal Counsel was directed to prepare a report on protection of assets for physicians and to disseminate this through Faculty publications. Council also directed Legal Counsel to prepare a brief for an *en banc* hearing in connection with the current fee guide for Workmen's Compensation payments.

Two recommendations on Professional Ethics were approved by the Council. One deals with Second Opinions, the other with Conflict of Interest statements for elected Faculty officials, councilors, and chairmen.

Standards for Second Trimester Abortions were approved on recommendation of the Subcommittee on Maternal Welfare. Funds were appropriated for the 1985/86 fiscal year for the Center for Health Education. Council directed that an in-depth review take place prior to commitment of additional monies to ensure that all avenues have been explored to make this organization self-supporting.

Various members were approved for Emeritus Membership, dues were waived for certain members on account of illness, and various other appointments were made.

JOHN SARGEANT CAE
Executive Director

Members in the News

Carlyle Crenshaw, Jr., MD, Baltimore, has been appointed to serve a three-year term on the Council on Resident Education in Obstetrics and Gynecology (CREOG), a national organization that promotes high standards of resident education in obstetrics and gynecology.

Dr. Crenshaw is professor and chairman of the department of obstetrics and gynecology at the University of Maryland School of Medicine and the chief of the obstetric and gynecologic service at the University of Maryland Hospital. He is a graduate of Duke University Medical School where he completed his residency. A member of the Society for Gynecologic Investigation, Dr. Crenshaw is president of the Obstetrical and Gynecological Society of Maryland.

• • •

Lee H. Haller MD, Gaithersburg psychiatrist, appeared as a discussant on "Ask Washington," a BIZNET cable production. The panel discussion on teenage depression and suicide aired in late June.

• • •

J. Andrew Sumner MD, assistant director of the Emergency Department at Franklin Square Hospital, was the recipient of an award from the American College of Emergency Physicians. Dr. Sumner and the Maryland Chapter of the organization received the first prize award in the Government Affairs category.

The winning project was a key contact program, teaming state legislators with emergency physicians in their districts. Dr. Sumner and others helped establish a nucleus of knowledgeable individuals who can be called on to testify on issues affecting emergency health care. Members testified in favor of tougher drunk driving legislation during the 1985 legislative session.

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*JAMA, Volume 248, No. 3, pages 336-339
Yearbook of Medicine, 1983, pages 66-67
Pediatric Infectious Disease,Volume 3, No. 6, pages 514-517

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Eric M. Fine, M.D., M.P.H.
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Office of Disease Control and Epidemiology Newsletter
PREVENTIVE MEDICINE ADMINISTRATION
MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE

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SEPTEMBER 1985

UPDATE: PUBLIC HEALTH SERVICE WORKSHOP ON HUMAN T-LYMPHOTROPIC VIRUS TYPE III ANTIBODY TESTING--UNITED STATES

The enzyme immunoassay (EIA) serologic tests to detect antibody to human T-lymphotropic virus type III (HTLV-III) are highly sensitive and specific, according to reports presented at a U.S. Public Health Service Workshop on HTLV-III Antibody Testing on July 31, 1985. The tests are currently being used at blood banks, plasma collection centers, health departments, and selected clinical centers throughout the United States.

The U.S. Food and Drug Administration reported cumulative HTLV-III antibody test data from more than 1.1 million units of blood collected at 155 centers through June 16, 1985. Of these, 2,831 (0.25%) were reported as positive based on a repeatedly reactive EIA test. The pattern of positive tests varied slightly in different regions of the country and by test kit used.

The Atlanta Region of the American Red Cross (ARC) and CDC reported data from testing more than 51,000 blood donors, of whom 0.23% were repeatedly reactive by the Abbott EIA method.* Among the specimens from 106 blood donors with repeatedly reactive tests, 34 (32%) were strongly reactive (ratio of specimen absorbance to cutoff value 7.0 or greater). EIA tests categorized as strongly reactive correlated highly with both positive Western blot tests (94%) and culture for HTLV-III/lymphadenopathy-associated virus (LAV) (56%).

Of 220 donors whose tests were initially reactive and subsequently negative, as well as a random sample of 50 with an initially negative EIA test, none had either a positive Western blot test or positive culture. Among those donors notified and interviewed to date, 16 (89%) of 18 with strongly reactive EIA tests had identifiable risk factors for HTLV-III/LAV infection, while none of 20 with weakly reactive tests had identifiable risk factors.

*Use of trade names is for identification only and does not imply endorsement by CDC or the U.S. Public health Service.

To determine the sensitivity of the Abbott EIA test in high-risk persons, virus isolations were attempted from homosexual men attending a clinic for sexually transmitted diseases in San Francisco, Calfornia. None of 70 men with negative HTLV-III antibody tests had a positive culture, while 43 (60%) of 72 with repeatedly reactive tests were culture-positive. Among the 72 EIA-positive sera in this portion of the study, 70 (97%) were considered to be highly reactive. Ninety-seven percent of those EIA-positive specimens tested to date have had a positive Western blot test.

Data from other blood banking organizations paralleled the findings of the ARC/CDC study in suggesting that approximately one-third of EIA-positive sera from blood donors were strongly reactive, regardless of the test kit used. Donors with strongly reactive EIA tests were also highly likely to have positive Western blot tests and to have positive EIA tests by other test kits.

Weekly reactive EIA tests correlated poorly with positive Western blot tests and were judged to be nonspecific for HTLV-III/LAV infection. The reason for nonspecific test reactivity is unknown, but proposed refinements in the test may eliminate many of the low level reactions.
Reported by Center for Drugs and Biologics, U.S. Food and Drug Administration, AIDS Branch, Division of Viral Diseases, Center for Infectious Diseases, Centers for Disease Control.
SOURCE: Centers for Disease Control (CDC), Morbidity and Mortality Weekly Report (MMWR), August 9, 1985/Vol. 34/No. 31.

HTLV-III ANTIBODY TESTING - MARYLAND

The Chesapeake Region of the American Red Cross has completed 18 weeks of donor screening as of August 16, 1985. Data from the first 16 weeks of donor screening indicates more than 50,000 donors were screened and 0.2% were repeatedly positive by ELISA.

The Maryland Alternate Test Site Program, which offers high risk individuals an alternative to donating blood for learning their antibody status, began May 23, 1985. From May 23 to July 31, 1985, 281 persons received pretest counseling regarding HTLV-III antibody testing. Of 237 who decided to be tested, 76.8% were seronegative, 14.8% were seropositive, and 8.4% of the results were pending at the time of this report. Ninety-four (94%) of the seropositive by ELISA were also positive by Western Blot. Data from the initial 73 participant questionnaires indicates that nearly 92% of the participants were male and 83.6% of the men listed "Gay or Bisexual" as one of their risk factors. During May-July 1985, the Maryland AIDS hotline handled more than 900 inquiries from the public pertaining to AIDS and/or HTLV-III testing. Alternate Test Site participants are self-referred; therefore, data arising from this program is not generalizable to either the entire at risk population or to the general population.

Information regarding donor screening has been submitted by Dr. Deborah Douglas, Medical Director, American Red Cross, Baltimore Regional Chapter.

.

AWARENESS AND BELIEFS ABOUT ACQUIRED IMMUNODEFICIENCY SYNDROME AIDS)

TABLE 1. Percentage of respondents aware of acquired immunodeficiency syndrome (AIDS)*--New York City, United States, June 1985

Respondents' characteristics	Responses (%)	
	New York City	United States
Age		
18-34 yrs.	91	96
35-49 yrs.	97	96
≥ 50 yrs.	95	92
Sex		
Male	95	94
Female	94	95
Race		
White	95	95
Black	95	93
Education		
Nonhigh-school graduate	90	85
High-school graduate	95	96
College graduate	98	99
Total no. respondents	**1,023**	**1,545**

*Awareness was determined by answering "yes" to the question: "Have you heard or read about a disease called AIDS?"

TABLE 2. Beliefs about acquired immunodeficiency syndrome (AIDS)--New York City, United States, June 1985

Statement	Responses (%)											
	United States			New York City			U.S. teen			N.Y.C. teen		
	T	F	U*	T	F	U	T	F	U	T	F	U
True												
Some people get AIDS when they receive blood transfusions.	92	3	5	90	6	4	86	11	3	80	16	4
Drug users who share needles have a higher risk of getting AIDS.	84	8	8	86	9	5	79	18	3	83	14	3
Most people with AIDS are homosexual men.	80	12	7	73	21	6	75	23	2	69	28	3
Some wives and girlfriends of drug users have gotten AIDS.	67	15	18	71	15	14	61	34	5	63	25	12
False												
You can get AIDS by shaking hands with someone who has it.	9	81	9	13	80	7	12	86	2	12	84	4
You can get AIDS by being in a crowded place with someone who has it.	9	81	9	15	78	7	14	84	2	14	81	5
Women cannot get AIDS.	6	88	6	8	87	5	8	90	2	12	86	2

*True; False; Unknown.

SOURCE: Centers for Disease Control (CDC), Morbidity and Mortality Weekly Report (MMWR), August 23, 1985/Vol. 34/No. 33.

THE MAGNITUDE OF THE SEXUALLY-TRANSMITTED DISEASES (STD) PROBLEM

- o The total cost of STD is estimated to exceed $2 billion annually.

- o The cost of gonorrhea alone exceeds $1.1 billion, a per capita cost of $5.00 each year to treat this infection.

- o An estimated 10 million cases of STD threaten the health of Americans, primarily adolescents and young adults each year:

  - 2.0 million cases of gonorrhea
  - 2.5 million cases of nongonococcal urethritis
  - 2.0 million cases of mucopurulent cervicitis
  - 90,000 cases of syphilis
  - 200,000-500,000 cases of genital herpes
  - 200,000 cases of hepatitis B
  - 3.0 million cases of chlamydia
  - 1.0 million cases of human papillomavirus
  - 3.0 million cases of trichomoniasis

- o 2.5 million teenagers are affected with an STD annually.

- o 65 percent of all STD cases occur among persons less than 25 years of age.

- o The most serious public health complications caused by STD are pelvic inflammatory disease (PID), infertility, ectopic pregnancy, adverse pregnancy outcome, infant pneumonia, infant death, mental retardation, and neoplasia.

- o Women and children bear an inordinate share of the physical and emotional burden of STD.

- o Involuntary infertility, a sizeable portion of which is secondary to STD, increased during the 1970's and into the 1980's. Requests for infertility services to private physicians exceeded 2 million visits in 1982.

- o Prenatal STD also produce adverse effects on both pregnancy outcome and maternal/infant health. Many of these adverse outcomes are entirely preventable.

- o Ectopic pregnancy has increased dramatically during the last 15 years. In 1982, it accounted for more fetal loss than stillbirths.

- o At least six cancers have been associated with different STD:
  - cervical intraepithelial neoplasia
  - vulvar carcinoma
  - anal carcinoma
  - penile carcinoma
  - hepatocellular carcinoma
  - kaposi's sarcoma

For more information contact the Venereal Disease Control Program at (301)-225-6688 or your local Health Department.

SOURCE: Centers for Disease Control, Atlanta, Georgia.

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Today's Psychiatry

What to Treat: Anxiety or Depression?

LINO COVI MD

One source of confusion for both epidemiological researchers and clinicians is that psychiatric disorders seldom occur in pure form and often coexist in a given patient. One of the most common combined occurrences is that of anxiety and depression.

A recently completed national epidemiological survey[1] found a higher incidence of anxiety and a lower level of depression in Baltimore than in the other sites surveyed, New Haven and St. Louis. Does this correspond to the practicing physician's experience? There is a difference between disorders prevailing in the community and disorders seen in the treatment setting.

For almost all psychiatric disorders, larger proportions of patients surveyed reported visits to mental health specialists than to general medical providers.

Several years ago a study (using, in part, data collected at Hopkins) showed that psychiatric outpatients diagnosed as depressed had higher absolute levels of anxiety than outpatients classified as anxious. The diagnosis of depression was determined by much higher severity levels of depressive symptoms compared to anxious symptoms. Conversely, anxious patients had much higher levels of anxious symptoms than of depressive symptoms.[2]

Because of the mixture of symptoms, it is easy in practice to focus on one set of symptoms and neglect the other, perhaps more important, set of symptoms. As a result of selective focus, a benzodiazepine may be prescribed for a chronic depression; the patient may remain too long on this type of drug, benefit little, develop tolerance, and eventually experience increased symptoms. Accurately distinguishing the two disorders is not an easy task; clinical researchers long have been aware of this difficulty.

In recent years, two simple scales have been used in clinical psychopharmacological studies to clarify the relationship between depressive and anxious symptoms in a patient. These scales also have been introduced recently in international studies.[3] They can be used in the office by inquiring about component complaints. If the depression scale (Raskin) is higher, the patient probably can be diagnosed as depressive; if the anxiety scale is higher (Covi) an anxiety diagnosis may be more probable. A total score of 7 on either scale usually requires psychiatric treatment.

Committee on Emotional Health, Gary W. Nyman MD, Chairman; Lino Covi MD, Editor.

References

1. Robins, L.N. *et al.* "Lifetime Prevalence of Specific Psychiatric Disorders in Three Sites." *Arch Gen Psychiatry* 41(1984):949–58.

2. Prusoff, B. and Klerman, G.L. "Differentiating Depressed from Anxious Neurotic Outpatients." *Arch Gen Psychiatry* 30(1974):302–09.

3. Covi, L. and Lipman, R.S. "Primary Depression or Primary Anxiety? A Possible Psychometric Approach to a Diagnostic Dilemma." *Clinical Neuropsychopharmacology* 7(1984):924–25.

not at all	somewhat	moderately	considerably	very much	
					Covi Anxiety Scale
1	2	3	4	5	*Verbal Report:* Feels nervous, shaky, jittery, jumpy; suddenly scared for no reason; fearful, apprehensive; tense or keyed up; has to avoid certain things, places, activities because of getting frightened; finds it hard to keep mind on task.
1	2	3	4	5	*Behavior:* Appears frightened, shaking, restless, apprehensive, jumpy, jittery.
1	2	3	4	5	*Somatic Symptoms of Anxiety:* Unjustified sweating, trembling; heart pounding or racing; trouble getting breath; hot or cold spells; restless sleep; going unjustifiably more frequently to bathroom; discomfort at pit of stomach; lump in throat.
					Raskin Depression Scale
1	2	3	4	5	*Verbal Report:* Feels blue; talks of feeling helpless, hopeless, or worthless; complains of loss of interest; may wish to be dead; reports of crying spells.
1	2	3	4	5	*Behavior:* Looks sad; cries easily, speaks in a sad voice; appears slowed down; lacking energy.
1	2	3	4	5	*Secondary Symptoms of Depression:* Insomnia or hypersomnia; gastrointestinal complaints; dry mouth; history of recent suicide attempt; lack of appetite; difficulty in concentrating or remembering.

Source: Covi, L. and Lipman, R. S. "Primary Depression or Primary Anxiety? A Possible Psychometric Approach to a Diagnostic Dilemma." *Clinical Neuropsychopharmacology* 7(1984): 924–25.

Maryland Oncology Newsletter

The Management of Primary Carcinoma of the Breast

Once the diagnosis of a breast cancer is made, the patient can be managed by surgery or radiation therapy.

Surgery is the most effective and well-studied therapeutic modality in the management of this disease. There are several surgical approaches for local and regional control of carcinoma of the breast. In the 1890s, William Halsted publicized *radical mastectomy* in which the breast, the two underlying pectoralis muscles and the axillary contents are removed. This became the standard surgical approach. The addition of internal mammary lymph node dissection and/or supraclavicular lymphadenectomy did not have an impact on the survival. In the 1950s, *modified radical mastectomy* replaced the radical operation. In this approach, the breast and the axillary contents are removed preserving the pectoralis muscles. Radical mastectomy is still recommended in patients with tumors that invade the pectoral fascia or muscle.

However, a question was raised: Should all women with cancer of the breast be treated by total removal of their breasts even if the tumor is detected early and is small? In 1954, Mustakallio from Finland reported that *lumpectomy* (also known as *tylectomy* or *wedge resection*) and radiation therapy seemed to result in equal survival to radical mastectomy. Two major studies confirmed the safety of such an approach; the first reported in 1972 was from Guy's Hospital in England, and the second reported in 1985 by the National Adjuvant Breast Project (NSABP) from the United States.[1] In this large study, patients presenting with small carcinomas (relative to the size of the breast) located in the periphery of the breast, with no nipple involvement, were randomized to one of the following treatments: (1) modified radical mastectomy, (2) lumpectomy and axillary dissection, or (3) lumpectomy, axillary dissection, and radiation (5000r) to the breast. Axillary dissection was carried out on all patients to identify those with lymph node metastases. These patients were then treated with the same adjuvant chemotherapy. The margins of the lumpectomy had to be free of tumor histologically. The results revealed that at five years there was no significant difference in survival. However, there was a higher incidence of local recurrence in the group that received lumpectomy with axillary dissection and no radiation therapy. These patients were then treated by total mastectomy, and their overall survival was not affected.

It must be emphasized that (1) not all breast cancer patients are eligible for tylectomy or lumpectomy. Patients with large or extensive tumors, edema or involvement of the skin, involvement of pectoral fascia or muscle, or inflammatory carcinoma are not candidates for such an approach. (2) Patients considered for lumpectomy must have no clinical or mammographic evidence of other tumors in the breast. (3) Close follow-up of those patients is essential to rule out early recurrences in the remaining portion of the breast. Patients found to have tumor in the axillary lymph nodes should receive one course of adjuvant chemotherapy after surgery, followed by radiation to the breast. After completion of radiation therapy the remainder of the planned adjuvant chemotherapy is given.

There are advantages and disadvantages to lumpectomy. The advantages include: excellent cosmesis, no need for reconstructive surgery, normal sensation, same survival as total mastectomy, and the patient psychologically feels that she has retained her femininity. The disadvantages include: high local recurrence rates if the breast is not irradiated, nonfunctioning breast after irradiation, the psychological impact of the possibility of developing another cancer in the same breast, and the unknown long-term effect. Daily outpatient visits for 5 to 6 weeks to receive radiation therapy may be inconvenient. Furthermore, large breasts do not tolerate radiation well.

Radiation therapy plays a major role in the management of patients with primary breast carcinoma. If a patient with proved carcinoma of the breast refuses surgery, she can be treated by radiation. There are three main types of irradiation: (1) External irradiation to the breast only, usually used after lumpectomy. (2) External radical irradiation, in which the breast or the chest wall (after modified radical or radical mastectomy), the axilla, supraclavicular, and internal mammary areas are irradiated. This is similar to performing supraradical surgery and is not recommended after radical or modified radical mastectomy because it does not improve the survival and renders the patient very labile to chemotherapy. However, it does reduce the incidence of local recurrence. (3) Interstitial irradiation in which radium needles are implanted in the breast tumor or after incomplete lumpectomy (that is, with positive margins and the patient refuses further surgery). This also can be used in addition to the external beam.

Radiation therapy also plays a major role in the management of patients with bone and brain metastases. Metastases in weight-bearing bones and spine can be treated by radiation therapy to avoid pending fractures or paralysis due to spinal collapse. It is the most effective treatment in the management of bone pain. Brain metastases are treated exclusively by radiation therapy. Steroids are used to reduce brain edema.

If you have questions, please call or write the Surgical Oncology Program at the University of Maryland Medical System, Room N13E02, Baltimore, Maryland 21201 (301-528-5224).

Finally, patients with carcinoma of the breast succumb to distant metastases and not to local or regional recurrences. Therefore, adjuvant systemic therapy is highly recommended in those patients with high risk of metastases, such as patients with one or more involved lymph nodes in the axilla.

Reference

1. Fisher, B. and members of NSABP. "Five-year Results of a Randomized Clinical Trial Comparing Total Mastectomy and Segmental Mastectomy with or without Radiation in the Treatment of Breast Cancer. *N Engl J Med* 312(1985):665–73.

Tumor Conference is held weekly on Fridays between 8 and 9 a.m. in Room N13E28. This is an open meeting; any physician is welcome to attend. Physicians can present cases, but please call before Friday to schedule your case, and bring the pathological slides with you.

E. GEORGE ELIAS MD
University of Maryland, Surgical Oncology Program

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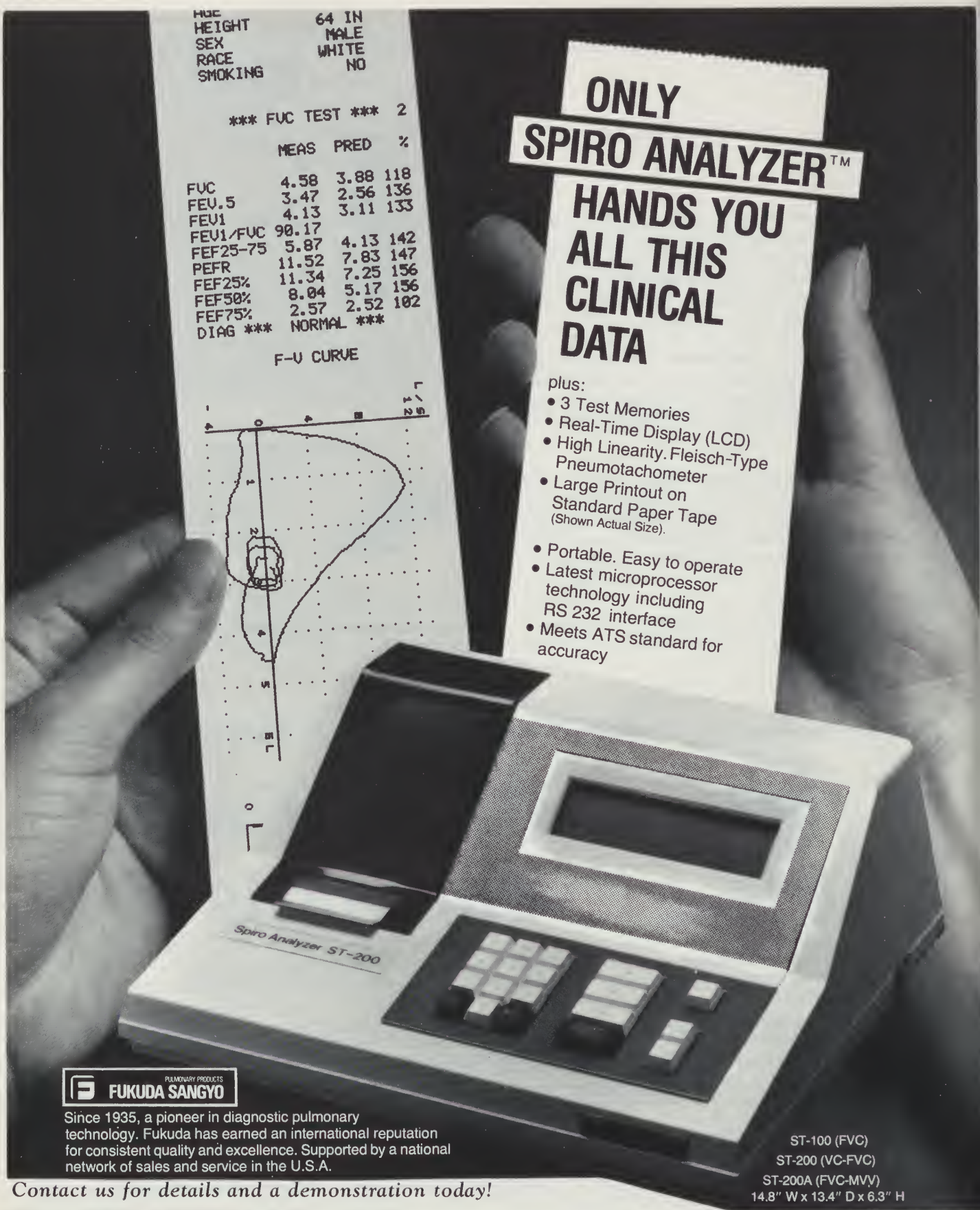
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The Library Page

Do It Yourself MEDLINE

On Saturday, June 29, eighteen physicians and other health care professionals gathered in the Faculty's Osler Hall for a one-day course on basic computerized literature searching. The purpose of the course was to instruct health professionals in searching techniques so they would be able to efficiently and effectively use their home and/or office computers to search MEDLINE. The National Library of Medicine's MEDLINE is useful for most practicing physicians and is available from a variety of database vendors. The basic searching techniques taught in this course are applicable regardless of the vendor used.

The course was a condensed version of the three-day course taught at the National Library of Medicine in Bethesda, Maryland. Until now, the National Library of Medicine has required that individuals complete the three-day course before they could be granted direct access to the MEDLINE data base. The National Library of Medicine has determined that completion of the condensed course satisfies this requirement. In addition to MEDLINE, participants also will have access to all other MEDLARS databases, including CANCERLINE and TOXLINE. Participants earned Category I CME credits.

Fitting a MEDLINE searching class into a single day requires an intense and demanding schedule for instructors and students. Much of the day is spent examining the National Library of Medicine's principles for indexing medical literature. To efficiently and effectively search for a topic in MEDLINE, the searcher needs to understand how the topic is indexed in the MEDLARS system and also how to logically combine subjects to narrow the search to articles on the specific topic. The prospective searchers were taught techniques that would reduce the amount of time needed to conduct a search, thus lowering the cost.

The response from the participants indicated the class was quite successful. Even participants who did not intend to do their own searches believed they would be more enlightened users of the search services of their libraries as a result of the course.

It appears that courses of this nature are wanted by Faculty members and by the medical community in Maryland. The Faculty Library will sponsor a second workshop on computerized literature searching this Fall. Interested physicians should contact Joseph Jensen, the Faculty Librarian, at 539-0872, x219 for details.

ADAM SZCZEPANIAK
Associate Librarian

Medical and Chirurgical Faculty of the State of Maryland Library, 1211 Cathedral Street, Baltimore, MD 21201. Joseph E. Jensen, Librarian

Selected Medical Literature Searches

The following are among the computerized medical literature searches provided to Med-Chi members during June 1985.

	Number of Citations
1. Behavior therapy and hyperphagia in adolescence	14
2. Complications of inguinal hernia surgery	28
3. Desquamative pulmonary fibrosis	13
4. Etiology and diagnosis of brain abscess	24
5. Netherton's syndrome	9
6. Organization and administration of hospital-based ambulatory surgery	35
7. Predictability of suicide	29
8. Private practice versus hospital outpatient clinics	16
9. Respiratory insufficiency and asthma	15
10. Rhinitis medicamentosa	10

If you would like a copy of one of these searches or a search run on any biomedical topic, call or write the library.

SUSAN E. HARMAN
Reference and Circulation Librarian

Future Med-Chi Meetings

1986 Annual
April 16–18
Baltimore Plaza Hotel

1986 Semiannual
September 10–14
Montreal

September 14–17
Post-Convention Trip
Chateau Frontenac
Quebec City

1987 Semiannual
Mid-September
Maui, Hawaii

1988 Semiannual
September 14–18
Bermuda

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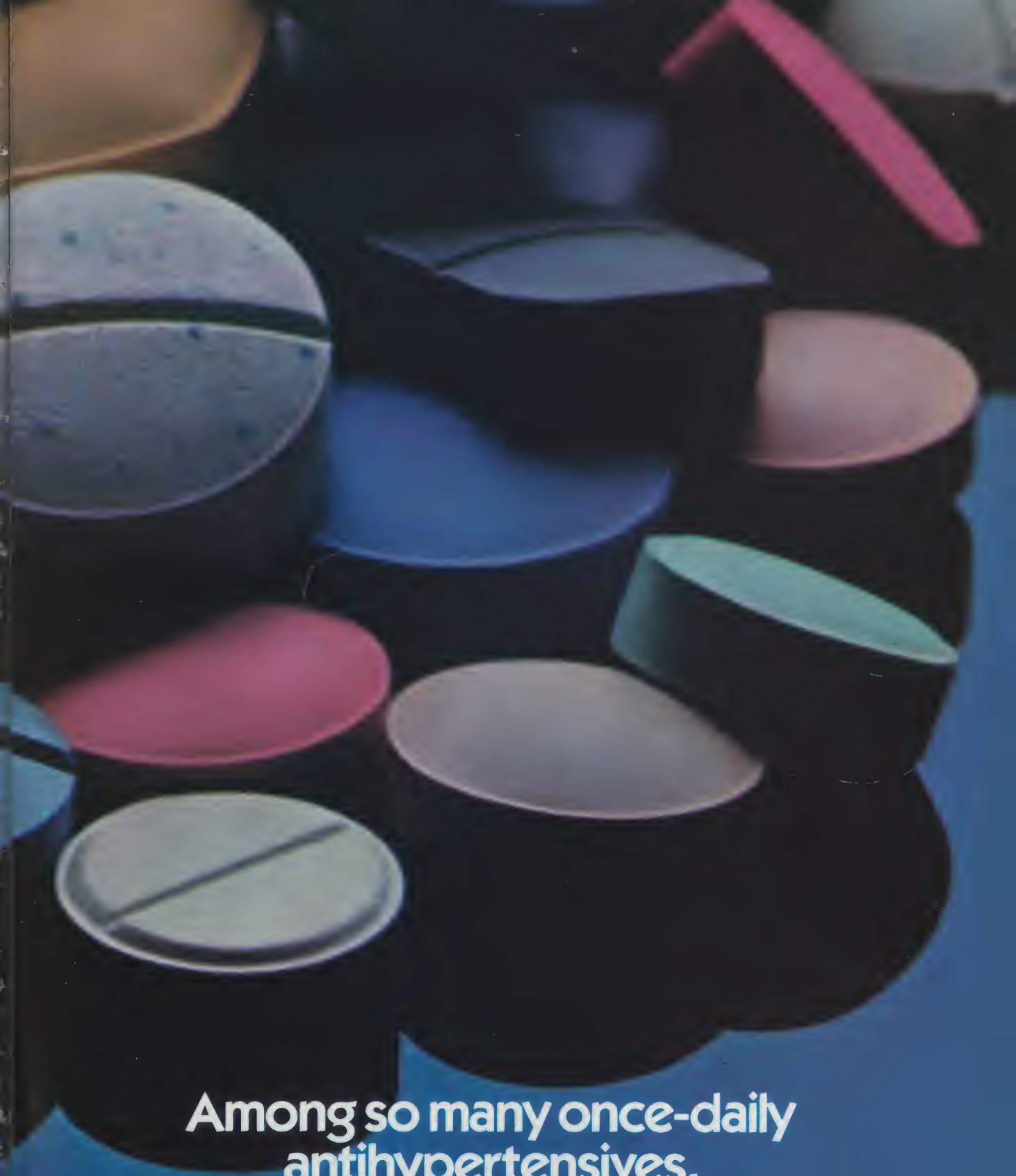
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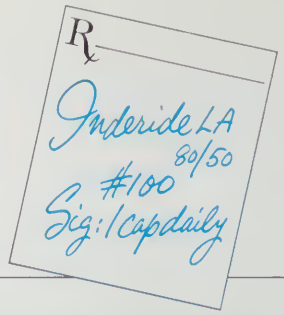
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Propranolol hydrochloride (INDERAL®):
Propranolol is contraindicated in: 1) cardiogenic shock; 2) sinus bradycardia and greater than first degree block; 3) bronchial asthma; 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with propranolol.

Hydrochlorothiazide:
Hydrochlorothiazide is contraindicated in patients with anuria or hypersensitivity to this or other sulfonamide-derived drugs.

WARNINGS

Propranolol hydrochloride (INDERAL®):
CARDIAC FAILURE. Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated, and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or propranolol should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of propranolol therapy. Therefore, when discontinuance of propranolol is planned, the dosage should be gradually reduced and the patient carefully monitored. In addition, when propranolol is prescribed for angina pectoris, the patients should be cautioned against interruption or cessation of therapy without the physician's advice. If propranolol therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute propranolol therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

THYROTOXICOSIS: Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol does not distort thyroid function tests.

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

MAJOR SURGERY. The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

Nonallergic Bronchospasm (eg, chronic bronchitis, emphysema)—PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD, IN GENERAL, NOT RECEIVE BETA BLOCKERS. INDERAL should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

DIABETES AND HYPOGLYCEMIA: Beta-adrenergic blockade may prevent the appearance of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more difficult to adjust the dosage of insulin. Hypoglycemic attacks may be accompanied by a precipitous elevation of blood pressure.

Hydrochlorothiazide:
Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. In patients with impaired renal function, cumulative effects of the drug may develop.

Thiazides should also be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Thiazides may add to or potentiate the action of other antihypertensive drugs. Potentiation occurs with ganglionic or peripheral adrenergic-blocking drugs.

Sensitivity reactions may occur in patients with a history of allergy or bronchial asthma.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

PRECAUTIONS

Propranolol hydrochloride (INDERAL®):
GENERAL: Propranolol should be used with caution in patients with impaired hepatic or renal function. Propranolol is not indicated for the treatment of hypertensive emergencies.

Beta-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should be told that propranolol may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

CLINICAL LABORATORY TESTS: Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS: Patients receiving catecholamine-depleting drugs, such as reserpine, should be closely observed if propranolol is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity, which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY. Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies, in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

PREGNANCY. Pregnancy Category C. Propranolol has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximal recommended human dose. There are no adequate and well-controlled studies in pregnant women. Propranolol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS. Propranolol is excreted in human milk. Caution should be exercised when propranolol is administered to a nursing mother.

PEDIATRIC USE. Safety and effectiveness in children have not been established.

Hydrochlorothiazide:
GENERAL. Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals.

All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance, namely: hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Medication such as digitalis may also influence serum electrolytes. Warning signs, irrespective of cause, are: Dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.

Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present, or during concomitant use of corticosteroids or ACTH.

Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia can sensitize or exaggerate the response of the heart to the toxic effect of digitalis (eg, increased ventricular irritability). Hypokalemia may be avoided or treated by use of potassium supplements, such as foods with a high potassium content.

Any chloride deficit is generally mild and usually does not require specific treatment, except under extraordinary circumstances (as in liver or renal disease). Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt, except in rare instances when the hyponatremia is life-threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy.

Insulin requirements in diabetic patients may be increased, decreased, or unchanged. Diabetes mellitus which has been latent may become manifest during thiazide administration.

If progressive renal impairment becomes evident, consider withholding or discontinuing diuretic therapy.

Thiazides may decrease serum PBI levels without signs of thyroid disturbance.

Calcium excretion is decreased by thiazides. Pathologic changes in the parathyroid gland with hypercalcemia and hypophosphatemia have been observed in a few patients on prolonged thiazide therapy. The common complications of hyperparathyroidism, such as renal lithiasis, bone resorption, and peptic ulceration have not been seen. Thiazides should be discontinued before carrying out tests for parathyroid function.

DRUG INTERACTIONS: Thiazide drugs may increase the responsiveness to tubocurarine.

The antihypertensive effects of thiazides may be enhanced in the postsympathectomy patient. Thiazides may decrease arterial responsiveness to norepinephrine. This diminution is not sufficient to preclude effectiveness of the pressor agent for therapeutic use.

PREGNANCY. Pregnancy Category C. Thiazides cross the placental barrier and appear in cord blood. The use of thiazides in pregnancy requires that the anticipated benefit be weighed against possible hazards to the fetus. These hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult.

NURSING MOTHERS. Thiazides appear in human milk. If use of the drug is deemed essential, the patient should stop nursing.

PEDIATRIC USE. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Propranolol hydrochloride (INDERAL®):
Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: Bradycardia, congestive heart failure, intensification of AV block, hypotension; paresthesia of hands; thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud type.

Central Nervous System: Lightheadedness, mental depression manifested by insomnia, lassitude, weakness, fatigue, reversible mental depression progressing to catatonia, visual disturbances; hallucinations, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Gastrointestinal: Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: Pharyngitis and agranulocytosis; erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory: Bronchospasm.

Hematologic: Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-Immune: In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: Alopecia; LE-like reactions; psoriasiform rashes, dry eyes; male impotence; and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes, and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

Hydrochlorothiazide:
Gastrointestinal: Anorexia, gastric irritation, nausea, vomiting, cramping; diarrhea, constipation; jaundice (intrahepatic cholestatic jaundice); pancreatitis; sialadenitis.

Central Nervous System: Dizziness, vertigo, paresthesias; headache, xanthopsia.

Hematologic: Leukopenia, agranulocytosis; thrombocytopenia, aplastic anemia.

Cardiovascular: Orthostatic hypotension (may be aggravated by alcohol, barbiturates, or narcotics).

Hypersensitivity: Purpura, photosensitivity; rash; urticaria, necrotizing angiitis (vasculitis, cutaneous vasculitis); fever; respiratory distress, including pneumonitis; anaphylactic reactions.

Other: Hyperglycemia, glycosuria, hyperuricemia, muscle spasm, weakness, restlessness; transient blurred vision.

Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy withdrawn.

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HBP Commentary

Historical Notes: Measurement of Blood Pressure II

CAROL LEWIS

In July's "Commentary" we reviewed early attempts to measure blood pressure up to the last half of the nineteenth century. Present day sphygmomanometry has evolved as the result of almost a century of clinical and physiological research; we continue the story. We also present revised standards for categorization of blood pressure and for referral to medical care.

To a medical student, entering the medical wards of a hospital for the first time, present-day measurement of blood pressure appears to be a simple, routine procedure. Yet the evolution of this important, common clinical test required more than a century of research and experimentation by many famous physiologists and physicians to point to the ultimate solution of the problem of accurate, clinical blood pressure measurement. During the course of their experimentation, numerous investigators introduced many modifications, resulting in the production of a large number of devices to measure blood pressure. The great majority were cumbersome and impractical and did not withstand the tests of time and experience; only occasionally did they improve the original ideas and methods of procedure. This long series of experimental studies finally culminated in the simple technique now in use.[1]

Von Basch, a Viennese physician, is considered the father of clinical sphygmomanometry since he introduced (in 1876) the first practical device to indirectly measure blood pressure. It was employed by a number of physicians in clinical practice. Using von Basch's apparatus, Zadek, in 1881, published a long and comprehensive report on his own findings.[2] As a result of measurements done on a number of healthy men and women, he concluded that the upper limit of the normal pressure was 150 mm Hg, and that lower was 70 mm Hg, close to figures commonly accepted today. He also pointed out that the blood pressure was lower in children; that it increased after meals, in the afternoons, following exercise, and in high altitudes; and that it usually decreased with rest. These were remarkably accurate clinical observations. Von Basch in 1887 summarized his own experience with his apparatus (as well as that of other investigators) and predicted the very important role blood pressure measurements would play in future medicine.

In 1896 a marked advance in clinical sphygmomanometry was made by Scipione Riva-Rocci, who was professor of medical pathology at the University of Padua.[3] The apparatus he devised is the forerunner of the modern sphygmomanometer (Figure 1). The important feature was a compressing mechanism, consisting of a rubber tube or bag, 5 cm wide, which encircled the middle of the upper arm and was inflated by means of a hand bulb. The rubber bag was connected to a mercury or anaeroid manometer. The radial artery was simultaneously palpated at the wrist. At the instant before the oscillations disappeared, the level of the systolic pressure was read on the manometer. This method had the advantage of applying the pressure in a more even manner over a wide area, without the difficulties involved in the direct obliteration of the radial artery, necessitated by previous instruments.

Riva-Rocci wrote a long report that gave full credit to everyone who preceded him, unusual for those days. He even apologized for not having seen earlier a modification of von Basch's instrument; he asked readers' forgiveness for a lapse that may amuse today's practitioners.

> Not until my apparatus already had been completed did I become aware of the modification, my ignorance of it being the



Figure 1. The Riva Rocci Sphygmomanometer (1896). Note narrow 5 cm armlet. Reprinted from Master, A.M.; Garfield, C.I., Walters, M.B. *Normal Blood Pressure and Hypertension: New Definitions.* Philadelphia: Lea and Febiger, 1952.

HBP Commentary is contributed by the Maryland High Blood Pressure Commission, 201 W. Preston St., Baltimore, MD 21201 (301-225-5891). Editors: R. Patterson Russell MD, Past Chairman; Donald O. Fedder PharmBS, DrPH, Chairman; and Carol Lewis MPH, ScD, Executive Director.

consequence of my unfortunate habit of not keeping up with the literature on a subject before I undertake new ventures. I hope the reader will forgive me on the score of the vastness and diffusion of the current literature on any given subject.[4]

With the introduction of the Riva-Rocci apparatus in 1896, a new impetus was given to the measurement of blood pressure in clinical medicine. Many workers in different parts of the world employed this technique, and each set forth what he considered to be normal values. However, the values tended to be high (by about 10 percent) because of the narrow 5 cm armlets used; these were later replaced by a 12–14 cm cuff.[5]

One of the first men to use the Riva-Rocci apparatus in the United States was the famous neurosurgeon Harvey Cushing.[6] When Cushing saw the Riva-Rocci sphygmomanometer during a vist to Pavia, Italy, he quickly recognized that it was an essential for anesthetists during surgical procedures. As soon as he returned to Johns Hopkins he developed a new anesthesia chart to track patients' progress and insisted that blood pressure readings be taken during all operations. His first report on the subject in the *Annals of Surgery*, in 1902, dealt with avoidance of shock in major amputations using observations of blood pressure changes during surgery.

Further refinements in measurement came quickly. By 1901 Theodore Janeway and other investigators recognized the occurrence of distinctly different sounds during deflation of the cuff, still using the oscillometric method. In 1905 Nicolai Sergeyovitch Korotkoff, a Russian physician in St. Petersburg, described the auscultatory technique, which gave more accurate readings. Korotkoff devised this method because he needed it for a specific use in his surgical practice; he was one of a new school of vascular surgeons who were accustomed to using a stethoscope to determine whether a mass was solid tissue.

Korotkoff proposed listening to sounds instead of feeling for a pulse or lack of it:

> The sleeve of Riva-Rocci is placed on the middle ⅓ of the arm toward the shoulder. The pressure in the sleeve is raised quickly until it stops the circulation of the blood beyond the sleeve. Thereupon, permitting the mercury in the manometer to drop, a child's stethoscope is used to listen to the artery directly beyond the sleeve. At first no audible sound is heard at all. As the mercury in the manometer falls to a certain height the first short tones appear, the appearance of which indicates the passage of part of the pulse wave under the sleeve. Consequently, the manometer reading at which the first tones appear corresponds to the maximum pressure. With a further fall of the mercury in the manometer, systolic pressure murmurs are heard which change again to a sound. . . . Finally, all sounds disappear. The time at which the sounds disappear indicates a free passage of the pulse wave; in other words, at the moment the sounds disappear, the minimum blood pressure in the artery exceeds the pressure of the sleeve. Consequently, the reading of the manometer at this time corresponds to the minimum blood pressure.[7]

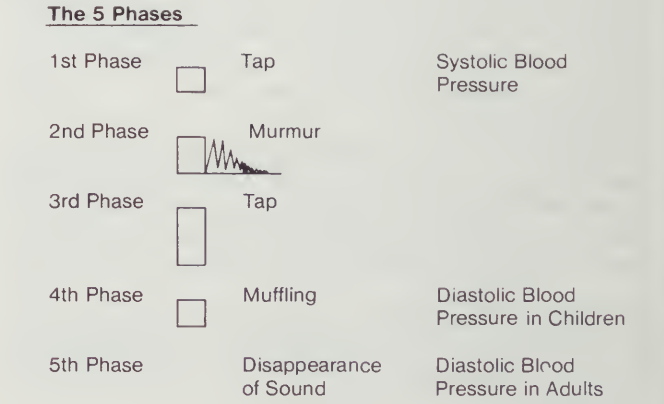
Korotkoff suggested that the systolic pressure be recorded at the very beginning of the first phase, and that the diastolic pressure be recorded at the *end* of the fourth phase, that is, when the sounds disappear. But in 1939, the Committee on Standardization of Blood Pressure Readings of the American Heart Association, and of Great Britain and Ireland, recommended that the point of muffling of the sounds (*beginning* of phase IV) be accepted as the diastolic pressure. However, in 1951 the Council for High Blood Pressure Research of the Scientific Council of the American Heart Association, through the Committee to revise "Standardization of High Blood Pressure Readings," concluded that the point of complete cessation of the sounds (phase V) is the best index of the diastolic pressure; this is what we use today.[8]

From the time of Stephen Hales' work in England, it took some 170 years to go from the measurement of blood pressure in a horse to accurate measurement of systolic and diastolic blood pressure in man. At last physicians no longer "measured" blood pressure by deciding whether the pulse at the wrist was hard or soft. By 1905 physicians could obtain actual numbers for blood pressure, numbers that allowed the study of hypertension to become a science. The new method began to be used widely.

However, the indirect method of measuring blood pressure was not initially accepted by academic medicine. For instance, the reaction of the *British Medical*

Figure 2.

Korotkoff Sounds



Journal in 1905 was that, by using these new devices, "we pauperize our senses and weaken clinical acuity."[9]

Nor was the Department of Surgery at Harvard convinced of the usefulness of the sphygmomanometer. In late 1901, while at a meeting in Cleveland, Harvey Cushing told George Crile about the new blood pressure apparatus he had brought to Baltimore and its advantages over the instrument Crile was using. This conversation led to an invitation to speak in Boston in January 1903.

At the Boston program, "Consideration of blood pressure," Crile spoke first on "My observations on the methods of control in the blood pressure," and then Cushing spoke on his "Blood pressure observations." As a result of the program, in February a printed circular was sent to all members of the Department of Surgery at Harvard requesting that a committee be formed to consider the "importance of blood pressure observations in surgical diagnosis and treatment." The committee, after long deliberation, decided that the skilled palpating finger was of greater value clinically for determination of the state of the circulation than any pneumatic instrument—a somewhat imperceptive appraisal of Cushing's recommendations.[10]

Harvey Cushing, reminiscing in 1930, had an interesting comment:

> I brought the first Riva-Rocci apparatus to this country from Pavia in 1901 when I came back to Hopkins from my year abroad and introduced it into the Johns Hopkins clinic where Briggs and Cook subsequently modified it and got it put in a box. The original apparatus was of course simply homemade, and was perhaps as good as any of the more recent ones. . . . But I am not so sure that the general use of the blood pressure apparatus in clinical work has done more than harm. Just as Floyer's pulse watch led to two previously unknown diseases, tachycardia and bradycardia, so the sphygmomanometer has led to the uncovering of the diseases of hypertension and hypotension, which have vastly added to the number of neurasthenics in the world.[11]

Not the view we hold today—but one that perhaps underscores the need to evaluate carefully newer methods of blood pressure measurement (for example, ambulatory monitoring, digital readouts) and the interpretation of their results and to remind us there is more to making the diagnosis of hypertension than merely documenting one or two elevated readings. The "gold standard" of blood pressure measurement remains the mercury sphygmomanometer.

References

1. Master, A.M.; Garfield, C.I.; Walters, M.B. *Normal Blood Pressure and Hypertension: New Definitions.* Philadelphia: Lea and Febiger, 1952: 11.
2. Ibid. 42–43.
3. Ibid. 26–29.
4. Comroe, J. *Exploring the Heart: Discoveries in High Blood Pressure and Heart Disease.* New York: W. Norton & Sons, 1984: 224–28.
5. Master, see reference 1, 28–31.
6. Harvey, A.M. "Harvey Williams Cushing: The Baltimore Period, 1896–1912." *Johns Hopkins Med J* 138(1976): 196–216.
7. Comroe, see reference 4.
8. Master, see reference 5.
9. Harvey, see reference 6.
10. Ibid.
11. Ibid.

Standards for Referral of Persons with Elevated Blood Pressure to Medical Care

We call your attention to the revised standards to be used by blood pressure screening and monitoring programs when referring adults (age 18 and older) to medical care. These standards have been published in the 1984 Report of the Joint National Committee on Detection, Evaluation and Treatment of Blood Pressure* and have been endorsed by the Maryland High Blood Pressure Commission, the American Heart Association, Maryland Affiliate, Inc. and other health organizations.

Persons will be referred to medical care from a screening or monitoring site if an average diastolic pressure (three measurements at each sitting; 5th phase Korotkoff sounds) is consistently ≥90 mm Hg and/or the average systolic is ≥140 mm Hg. The systolic level for referral has been lowered from ≥150 mm Hg to ≥140 mm Hg, so you may expect more HBP referrals from community sources. If recommendations for follow-up of DBP and SBP are different, the shorter recommended period supersedes, and a referral supersedes a recheck recommendation. *The standards as listed are for referral only and are not intended to serve as standards for the diagnosis and treatment of HBP.*

Diastolic Blood Pressure (mm Hg)	Recommended Follow-up
<85	Recheck within 2 years
85 to 89	Recheck within 1 year
90 to 104	Confirm promptly (not to exceed 2 months)
105 to 114	Evaluate or refer promptly to source of care (not to exceed 2 weeks)
≥115	Evaluate or refer immediately to a source of care

Systolic Blood Pressure (mm Hg) When DBP <90 mm Hg:	Recommended Follow-up
<140	Recheck within 2 years
140 to 199	Confirm promptly (not to exceed 2 months)
≥200	Evaluate or refer promptly to source of care (not to exceed 2 weeks)

* *Arch Intern Med* 144(1984):1045–7.



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One Minute with Diabetes

I am a 28-year-old office worker who has had diabetes for 16 years. I worry about problems with my feet. About every six months an ulcer will develop on one of my toes or under a callus on the bottom of my foot just back of the toes. It seems to occur after I wear "heels" to work. Healing occurs in a month or two with the use of antibiotics and soaking under the supervision of my physician. On one occassion osteomyelitis developed, and a portion of one toe had to be amputated. These ulcers do not hurt because my feet are numb. I am afraid that I may need an amputation of a foot someday. What can I do to prevent the recurrence of these ulcers and calluses?

Calluses and ulcers form on the feet as the result of pressure or trauma to the areas. These problems will be recurrent until the cause is corrected. Certainly a podiatrist or an orthopedist should evaluate the feet for correctness of balance and to be sure that there is no underlying osseous deformity. Footwear should be examined for proper design and fit. Often changing to properly fitted footwear will solve many of these problems. Switching from "heels" to oxfords will give a better distribution of the body weight to the feet. Wearing closed in shoes rather than an open-toed type will be protective to the toes.

Foot care is very important for the diabetic patient. Each evening the feet should be bathed in warm water, dried with a soft towel, examined for skin breaks or pressure points, and then massaged lightly with an emollient cream. A small area of increased warmth on the foot should be watched closely, because that is usually the first sign of a beginning problem.

The best possible control of the diabetes should be maintained at all times. Remember: preventing a foot infection or injury is much easier and more economical than treating the problem.

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Insurance Monitor

Claims Continue

According to figures reported by the American Medical Association, three times more malpractice claims are filed now than were a decade ago. In 1983, 16 malpractice claims were filed for every 100 physicians, an increase of 20 percent from 1982. Sixty percent of all obstetricians in the United States have been sued, and 20 percent of all obstetricians have been sued three or more times. In 1975, there were three malpractice verdicts of over $1 million; in 1982, there were 45.

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Premium Update

Because the number of malpractice claims filed against physicians and the amounts awarded in those claims continue to increase, insurance companies are forced to raise their professional liability rates.

In New York, the State Superintendent of Insurance recently approved a 52 percent rate increase; an obstetrician practicing on Long Island will pay annual insurance premiums of approximately $82,500, and a neurosurgeon in the same area will pay approximately $101,000.

In Maryland, the following rate increases were announced:

General Accident—overall 68 percent increase, effective April 1, 1985, plus an additional 40 percent increase effective July 1, 1985.

Medical Mutual—overall 29 percent increase, effective July 1, 1985.

Pennsylvania Casualty Company—overall 12 percent increase, effective July 1, 1985.

St. Paul—overall 25 percent increase, effective July 1, 1985.

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Massachusetts

According to the *Journal of Commerce*, Massachusetts physicians face at least a 100 percent rate increase in their malpractice premiums. The increases are needed because the State Insurance Commission reportedly is running three years behind in its rate-setting procedures.

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Pennsylvania

In November 1984 a jury in Philadelphia awarded $5.5 million to the family of a woman who died after contracting leukemia while being treated for ovarian cancer. One of the largest awards ever given in Pennsylvania, the case included an unusual $3 million in punitive damages against the four treating physicians. The court records have been sealed from the public.

Psychiatrists

The American Psychiatric Association malpractice insurance program will no longer cover sexual misconduct by therapist.

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Sources of Claims

The St. Paul Fire and Marine Insurance Companies, the nation's largest insurer of physicians, hospitals, and health-care services, released a study summarizing claims against its insured physicians. The five most frequently cited causes of malpractice claims were (in order):

(1) Failure to diagnose cancer
(2) Drug side effects resulting from improper treatment
(3) Failure to diagnose fractures or dislocations
(4) Failure to diagnose pregnancy related problems
(5) Postoperative complications

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The 1990s

Elizabeth Fee, Associate Professor at the School of Hygiene and Public Health of John Hopkins University, recently spoke to a New York symposium on health care financing and projected that by the 1990s, one-fourth of the U.S. population will be unable to afford health insurance, and medical care costs will comprise approximately 14 percent of the gross national product. According to William W. Lawrance, Director of the Life Sciences and Public Policy Program at Rockefeller University, in 1985 health care for Americans will account for about 11 percent of the GNP, or nearly $1 billion a day.

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Not Just Physicians

Malpractice suits filed against lawyers are increasing, and their insurance premiums are increasing at a corresponding rate. St. Paul Fire and Marine Insurance Co., the oldest continuous insurer of professional liability for lawyers, has increased rates an average of 121 percent in the 35 states where St. Paul writes coverage. Shand, Morahan & Co. has increased its lawyers' professional liability insurance rates as much as 450 percent.

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For more information or answers to your insurance questions, contact your insurance representative.

Medical Miscellany

Survey and Opinion Briefs

The Public Image of Physicians Revisited

Once again we examine the public image of physicians, an issue that is generating increasing discussion around the federation. Public image is also the target of a major campaign mandated by recent actions of the AMA's House of Delegates.

Survey research serves three distinct purposes when an issue such as the public image of physicians unfolds. These are to identify the emerging problem, to provide direction in developing effective messages and themes for an improvement campaign, and to test the actual impact of the campaign on public opinion. The first phase is over; the problem and its ramifications have been well delineated. The second phase is now under way.

In developing effective messages for a public image campaign, there are several major difficulties to confront. The foremost is the extreme complexity of the issue itself. So many different attitudes are involved: fees and incomes, personal contact with the physician, general faith in physicians, care for the poor and elderly. Where does one begin?

A good place to start is by looking for fundamental underlying attitudes that affect a number of opinions and provide a focal point for developing messages.

As part of this process, the American Medical Association, in cooperation with the American College of Emergency Physicians, commissioned telephone interviews with 1,000 U.S. adults in November 1984. The actual interviews were conducted by V. Lance Tarrance and Assoc., a Houston-based research firm.

Most doctors spend enough time with their patients.

	Percent
Agree	34
Disagree	61

Doctors' incomes are fair because of the importance of what they do and the many years of training they have to undergo.

	Percent
Agree	62
Disagree	33

Doctors don't care about people as much as they used to

	Percent
Agree	54
Disagree	42

Most men and women who become doctors today do so because they want (to help other people) (the money and prestige it brings).

	Percent
Help people	28
Money and prestige	44
Both	25

According to these data, a majority of Americans believe that physicians don't spend enough time with patients, don't care about patients as much as they used to, receive fair incomes, but are more likely to be motivated by money than by the desire to help people.

Of these four attitudes, the career motivation perception is the most fundamental because it strikes at the essence of why the public thinks doctors do what they do. But how strongly related is this viewpoint to the other three opinions?

Percent Agree	Why Doctors Practice		
	Help People Percent	Money Percent	Difference Percent
Spend enough time	47	24	23
Don't care as much	34	71	37
Incomes are fair	77	48	29

Americans who hold the "help people" position are much more likely to:

- agree that doctors spend enough time with patients
- disagree that doctors don't care as much as they used to
- agree that physicians' incomes are fair

At this initial stage of research, it is clear that underlying attitudes toward physicians' career motivations are very important to other image-related perceptions. In terms of developing messages for an image campaign, this basic belief in why doctors become doctors should be a major target.

Some possibilities include a focus on medical students and the reasons behind their career choice or on the changing demographics of the medical student/physician population, an issue also positively received by the American public.

There are a lot more women and blacks who are doctors than there used to be.

	Percent
Agree	78
Disagree	11

I think it's good that there are a lot more women and blacks who are doctors than there used to be.

	Percent
Agree	87
Disagree	8

Incorporating these positive attitudes in a larger message campaign would be a good strategy for improving general public perceptions of physicians. This focus on identifying underlying opinions and reinforcing positively viewed perceptions are but two examples of the ways that survey research can help in developing effective medical association communications.

If you have any questions or comments, contact Larry J. Freshnock PhD, Director, Survey and Opinion Research (312-645-4450).

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Diabetics Needed for Study of New Form of Insulin

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Unfortunately, there are children and adolescents who inadvertently "fall between the cracks" and have difficulty receiving services for medical, educational, and emotional needs. "Youth Who Don't Get Better: Untreatable or Untreated?" will be addressed by an interdisciplinary panel of seven professionals at the Seventh Annual Conference of the Maryland Interdisciplinary Council for Children and Adolescents (MICCA). It will be held on Saturday, November 9, 1985 from 9:00 a.m. to 12:30 p.m. at the Ford Building of the Sheppard and Enoch Pratt Hospital in Towson, Maryland.

The Medical and Chirurgical Faculty, a founding member, is one of the sixteen professional societies and organizations sponsoring the meeting. Barbara Starfield MD, Professor and Head of the Division of Health Policy at the Johns Hopkins School of Public Health and Hygiene will discuss "Children in Serious Need: An Epidemiologist's View." Barbara J. Howard MD will speak about "Individualizing Services: How About At Home?" "The Difficult Adolescent in Therapy: Who is in Charge?" will be presented by David Student MD. Theodore H. Kaiser MD will be Chairman and Moderator. Other topics include "Interagency Accountability: Can Due Process be Expedited?" "An Educational Dilemma: Too Young, Too Old, Too Complicated," and "Neuropsychological Deficits: A Description or a Prescription?"

Registration fee will be $15. A $5 fee applies to full-time students.

Information may be obtained by calling 301-484-7162 or writting Theodore H. Kaiser MD, Chairman, MICCA, Box 23, Stevenson, MD 21153.

PHYSICIAN PLACEMENT SERVICE

The Medical and Chirurgical Faculty of the State of Maryland maintains a Placement Service for the convenience of Maryland physicians, hospitals and communities in search of candidates for positions available in our state. A detailed description of such opportunities should be forwarded to the Physician Placement Service, 1211 Cathedral St., Baltimore, MD 21201; telephone 1-301-539-0872.

Physicians wishing to locate in Maryland are invited to submit a resumé to be kept on file with the Physician Placement Service. Candidates are requested to inform the Faculty when they are no longer available for consideration for opportunities which might be available in Maryland.

Journal announcements on the Classified Advertising page for Physician Placement Service are charged at the regular Classified Advertising rate.

Inside Med-Chi

The Importance of Medical Peer Review

Assuring that quality health care is rendered to the public has always been a primary concern for physicians. Today, quality assurance is becoming an even more serious concern for both physicians and patients because of the drastic changes occurring in health care delivery. With the current emphasis on cost containment, many people fear that quality of care may be sacrificed. The organization of the Peer Review Committee of the Medical and Chirurgical Faculty of Maryland was an effort to promote higher standards of medical care and to assure that the public receives health care from competent practitioners.

The purpose of the Faculty's Peer Review Committee as stated in the Faculty Bylaws is

> to review the practices of Maryland physicians practicing in institutions, offices, and other locations where medical care is rendered, for the purpose of evaluating the appropriateness of the care rendered, as well as the competence and efficiency of the physicians rendering it.

The committee is also responsible for reviewing the quality of care delivered by individuals under the supervision of physicians.

The Peer Review Committee evolved from the Mediation Committee by authorization of the House of Delegates in 1969 and was the result of extensive changes in the Medical Practice Act that were promulgated by the Faculty. The revised Act, which establishes a Commission on Medical Discipline, requires active participation by both state and local medical societies in the review process. Prior to 1969, the Faculty had no statutory responsibility and thus no defined role in dealing with physicians who had practice problems. The changes in the law permitted the Faculty to conduct investigations on the basis of any valid complaint coming to it concerning physicians practicing in the state. The change in the law has allowed the Faculty to begin dealing with the problem of the physician with serious practice difficulties who is not working for a hospital and consequently who has not been subject to peer review.

Under this law, the Peer Review Committee is an investigatory arm of the Commission on Medical Discipline. The Commission is a state agency empowered to act against a physician's license, from reprimand to revocation. The Commission is required to refer cases coming to its attention to the state or local medical society for investigation and report. All physicians in the state of Maryland, whether members or nonmembers of the medical society, come under the jurisdiction of the statute, and hence under the investigatory authority of the state and local medical societies. Immunity from liability is provided for members carrying out such review as well as for individual physicians, component and specialty societies, insurance carriers or others who report physicians "in good faith" for peer review of a physician's practice.

At the present time, there are twenty members of the Peer Review Committee. The need to represent *every* specialty in this committee has been obviated by the willingness of the statewide specialty groups to provide consultative services in specific cases.

Sources of complaints may include (but are not limited to) other physicians, patients, government or private agencies, and the Commission on Medical Discipline. The majority of cases referred to the Faculty Peer Review Committee come from the Commission. Some cases from Maryland Blue Cross and Blue Shield (which has its own Utilization Review Committee) are received by the Faculty when questions of the quality of care are raised.

Reviews conducted by the state peer review committee are carried out in a variety of ways, depending on circumstances. Upon receiving a complaint, the physician may be asked to appear before the entire committee or before some portion of the committee; or after review of the complaint, members of the committee may visit the physician in his or her office and review the practice in question, using guidelines created by the Peer Review Committee. On occasion, both approaches may be used. Following the investigation, the committee will make a recommendation to the Commission or the doctor, depending on the circumstances. These recommendations can range from no disciplinary action to formal action against a physician's license. Recommendations to the Commission on Medical Discipline for punitive measures against a physician's right to practice are made infrequently and only after the committee is completely sure that no other alternative exists. In 1984, only two licenses were revoked as a result of investigations by the Faculty Peer Review Committee.

The physician under review is entitled to a reasonable opportunity to explain his treatment and the right to have counsel present at any meeting. Proceedings of the committee are absolutely confidential by law. When problems are substantiated, the philosophy of the committee is to educate and assist the physician wherever possible. The committee's strong feelings toward reeducation have resulted in the development of a liaison between the committee, the Commission on Medical Discipline and the Department of Family Practice of the University of Maryland School of Medicine, to develop educational programs tailored to the specific needs of physicians who may be referred for such education.

Another aspect of the Peer Review Committee's responsibility has been the establishment of methodology of statewide peer review. The Faculty's Council has approved a number of recommendations of the committee, including the development of "Standards to be Used in Reviewing Physicians' Practices" and the "Peer

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Review Handbook." These standards and processes grew out of the difficulty experienced by committee members in conducting a reasonable, thorough, and fair review of physicians' practices. Component societies also use these standards as guidelines.

Strong emphasis should be placed on the fact that peer review is an educational process and not a punitive process. Its primary purpose is to assist physicians to remain in practice rather than to "discipline" them. It attempts to insure that quality care is being provided by physicians wherever they practice. In this way, the needs of the profession and the public are served. Once physicians understand what is involved and why the work is being done, the response is almost always positive. Today, many more physicians recognize peer review as an opportunity to improve their practice and to enhance their value to patients.

NINA C. CASEY
Public Relations/Membership Coordinator

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Osteoarthritis XI: Lumbar Spondylosis

IRA T. FINE MD

Lumbar spondylosis is the term applied to osteoarthritis at the intervertebral disc level. This process usually coexists with apophyseal osteoarthritis; the two together are referred to as degenerative spondylosis. Aging plays a crucial role in this type of arthritis. In a study performed by Schmorl and Junghanns (1971), evidence of degenerative spondylosis was found in 80 percent of males and 60 percent of females at age 50 and virtually all subjects by age 70.

Dr. Fine is Instructor in Medicine, Johns Hopkins University, School of Medicine, Baltimore, MD.

Osteoarthritis of the lumbar spine is a common source of musculoskeletal pain and one of the most frequent causes of disability in the United States. In a typical rheumatology practice, 20 percent of patients have back pain as their presenting complaint. This type of osteoarthritis is unique in that, unlike peripheral joint osteoarthritis, it affects two distinct articular systems: the intervertebral discs and the posterior diarthrodial or apophyseal joints.

Clinical Presentation

Symptoms associated with degenerative spondylosis are not unlike symptoms of osteoarthritis of the peripheral joints: chronic recurrent pain with acute episodes superimposed. Discomfort often is described as dull and aching. It is aggravated by movement and relieved by rest. Back pain predominantly caused by pathology at the level of the intervertebral disc may be accentuated by coughing or straining.

Location of pain due to degenerative spondylosis is variable. It is felt mainly in the low back at the area of spinal involvement. Pain may radiate up and down the paraspinal regions and extend to the buttocks.

On physical examination the patient with degenerative spondylosis may show localized tenderness, stiffness and spasm of paraspinal musculature, limitation of lumbar motion, and reversal of normal lumbar lordosis. Neurologic signs and symptoms may be apparent if a nerve root is encroached on by an osteophyte or irritated by synovitis of an apophyseal joint. Muscle weakness and peripheral sensory abnormalities such as numbness and paresthesias are seen with significant disease. Neurologic deficits also may be seen with disc protrusion occurring as a consequence of lumbar spondylosis (see pathophysiology section). Specific deficits are dependent on the area of protrusion and the nerve root that is irritated or compressed.

The presence of spondylosis does not imply symptoms of back pain. Many patients deny back symptoms despite gross radiographic changes.

Body Mechanics

To understand the pathophysiology of degenerative spondylosis, it is important to review the mechanics of the lumbar spine. The major functions of the spine as a whole are to protect vital structures, bear weight, and allow flexion and extension as well as lateral flexion and rotation. The vertebrae of the lumbar spine are built heavily to accommodate the significant stresses placed on them.

Vertebrae are linked by intervertebral discs and apophyseal joints. Each disc consists of an internal mass of gelatinous material (nucleus pulposus) surrounded by circumferential sheets of collagen with fibers that run obliquely (annulus fibrosus). The normal disc is crucial in maintaining the stability and dynamics of the spine. Apophyseal joints are true synovial joints with fibrous capsules lined by synovium. It is important when viewing the mechanics of the spine to consider the intervertebral disc and apophyseal joint as a unit. Spinal movement cannot occur at either the disc or apophyseal joint level alone. Similarly, pathology at one articular system will affect the other.

Pathophysiology

The occurrence of mechanical problems and degenerative changes is not unexpected in this heavily stressed area of the skeleton. Degenerative changes may occur within and around the intervertebral disc either as a sequela of acute disc herniation sustained earlier in life or as a result of the natural aging process. In the nucleus the chemical composition changes with age. The water content decreases. Adams and Muir (1976) showed qualitative changes in the nuclear proteoglycans and changes in their interactions with collagen. Drying with cleft formation, scarring, and neovascularization are in evidence. In the annulus, aging or degeneration distorts the arrangement of the fibers. The once clear distinction between the nucleus pulposus and annulus fibrosus is lost. These changes decrease resiliency, the characteristic of the disc that allows it to respond to stress. Disc space narrowing may develop. The disc becomes increasingly prone to posterior protrusion or prolapse into the spinal canal.

Clefts may appear at the bone ligament junction where the annulus fibrosus attaches to the vertebral rim. Periosteal elevation and subsequent osteophyte formation develop in this region around the vertebral rim. If multiple areas are involved, osteophytes can

meet and fuse. Bony overgrowths may form posterolaterally in relation to the intervertebral foramen with resultant pressure effect on the spinal nerve.

The intervertebral disc that has been altered with age allows abnormal stresses to be placed on the apophyseal joints. As noted, these joints are true synovial joints and develop changes similar to those observed in the osteoarthritic process of other synovial joints. Erosion of cartilage, sclerosis of articular bone, cyst formation, joint space narrowing, and osteophytes all are commonly observed. Osteophytes from the apophyseal joint may inhibit spinal movement and impinge on nerve roots passing through the intervertebral foramen. The resultant change at the apophyseal joint level ultimately may lead to fixation of the involved segment.

Primary disc degeneration and previous disc herniation are not the only inciting factors of lumbar spondylosis, although they are the most common. Previous trauma, infection, or metabolic disturbances may lead to spondylosis. Furthermore, osteoarthritis of the apophyseal joint may occur without significant disc disease as part of a generalized primary osteoarthritis. Apophyseal joint changes also may be seen as a result of conditions such as kyphosis, scoliosis, spondylolithesis, vertebral fractures, and inflammatory spine disease. Evaluation of patients with low back pain due to suspected osteoarthritis should include a complete history and physical examination, appropriate x-rays, scans, and laboratory studies to rule out other inciting factors.

Radiologic Findings

X-ray changes as a result of degenerative spondylosis have been alluded to in the previous discussion. With mechanical failure of the disc, the picture is one of disc space narrowing and reactive sclerosis of adjacent bone (Figure 1). Clefts and fissures in the nucleus pulposus and annulus fibrosus are recognized by the appearance of a gas vacuum phenomenon. With involvement of several discs, the spine may become shorter. Osteophytes may be seen clearly on radiographs (Figure 2). Oblique views may be employed to show encroachment by osteophytes on the intervertebral foramina.

The radiographic findings at the apophyseal joint level were discussed in a previous article and include cartilage erosion, articular bone sclerosis, cyst formation, joint space narrowing, and osteophyte formation.

X-ray changes consistent with degenerative spondylosis are common in the elderly population. Back pain also is common, and not always due to spondylosis, despite impressive radiographs. Several conditions associated with spondylosis have been discussed. Disease entities such as Paget's disease and primary as well as metastatic tumors should be additional considerations in the differential diagnosis of the patient with low back discomfort.

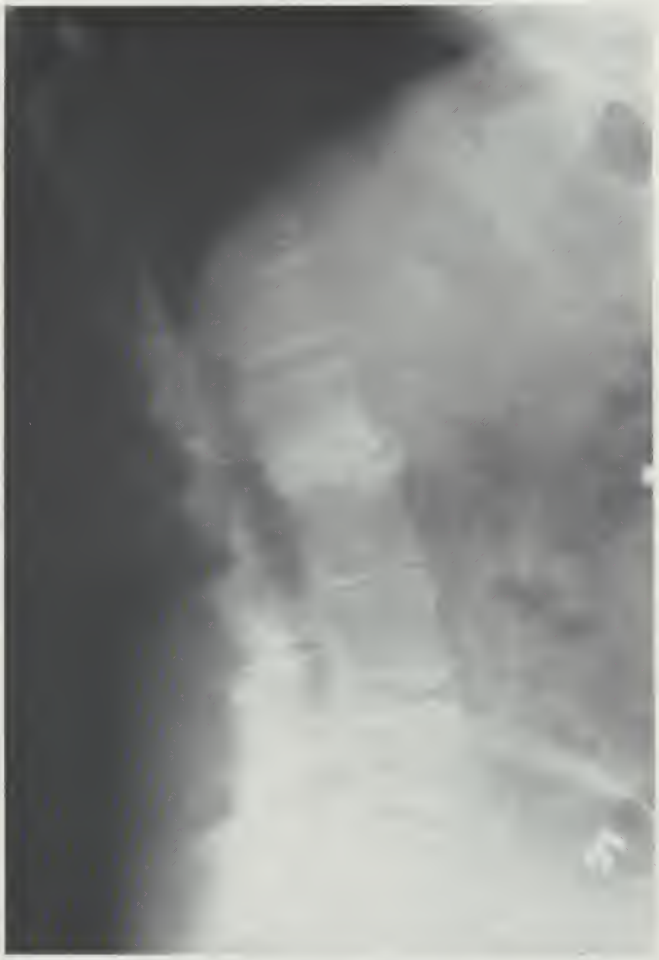


Figure 1. Disc space narrowing and reactive sclerosis at the vertebral end plates with osteophyte formation at the L 1–2 level.



Figure 2. Osteophytes are seen at several levels in this patient with lumbar spondylosis. Note the absence of disc space narrowing.

Treatment

Treatment must be tailored to the age and occupation of the patient, the extent of impairment, and the duration and severity of symptoms. Most patients respond to conservative management including rest, heat, analgesics, and anti-inflammatory agents. A firm mattress or bed board beneath the mattress may be helpful. Sedatives and muscle relaxants may be employed for severe pain and muscle spasm.

As acute symptoms subside, chronic discomfort may be managed with the use of a lumbosacral corset. In an attempt to minimize recurrent episodes of pain, exercises often are instituted to strengthen the anterior abdominal muscles and correct postural contributing factors. The physical therapist often plays a major role in the acute and chronic management of degenerative spondylosis.

Surgical intervention is generally not indicated. Indications for surgery include persistent or recurrent symptoms despite maximum medical treatment and persisting or advancing neurologic signs.

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Questionnaire

For the past three years the Maryland Chapter, Arthritis Foundation has sponsored a monthly series of articles on rheumatology related subjects (rheumatoid arthritis, lupus, osteoarthritis) in the *Maryland Medical Journal*. We would appreciate your assistance in the critique of this effort by responding to the following questions:

(*Please check one item only*)

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   - ____A. Family or General Practice
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   - ____C. Surgery and related subspecialties
   - ____D. Other
2. I read the Arthritis Foundation sponsored series articles:
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   - ____B. Most of the time
   - ____C. Half the time
   - ____D. Occasionally
   - ____E. Never
3. I find the Arthritis Foundation sponsored articles in the *Maryland Medical Journal*:
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   - ____B. Useful and informative most of the time
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   - ____D. Rarely useful and informative
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4. The Arthritis Foundation sponsored series in the *Maryland Medical Journal* should be continued:

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Prenatal Diagnosis of 45, X/46, XY

JAMES L. WAURIN MS, JOHN E. ADAMS MD, and THEODORE A. BARAMKI MD

Amniotic fluid cells in an initial sample showed a 45,X/46,XY pattern with 45,X cells confined to only one culture flask. A second sample showed the mosaicism to be evenly dispersed and subsequent pregnancy termination revealed a phenotypic normal male. Chromosome analysis of various tissues, however, revealed the 45,X/46,XY pattern.

Drs. Waurin and Adams are at the Department of Pathology, and Dr. Baramki is at the Division of Reproductive Endocrinology, Greater Baltimore Medical Center, Baltimore, MD 21204.

M.D. was referred to the Genetic Counseling Clinic of our Center with the indication of advanced maternal age (34). She was a para 2012, having lost one pregnancy in the seventh month for unexplained reasons. The family history was unremarkable on both sides. The initial amniocentesis was carried out at 17 weeks gestation. Questionable results from this sample prompted the patient to consent to a second amniocentesis at 21 weeks gestation. Results confirmed the initial findings. When these data were presented to the parents, they were counseled that mosaicism of the 45,X/46,XY type can manifest a phenotype having a wide spectrum ranging from normality to expression of the Turner's syndrome. Mild retardation is not uncommon.[1]

Cytogenetic Results

In the laboratory, amniotic fluid is added to three separate flasks of culture media arbitrarily designated A, B, and C. They are not centrifuged. Each flask is subsequently treated as an individual culture. Results from the first sample are listed in Table 1. After discovery of 45,X cells in only one of the culture flasks, it was theorized that a divisional error had taken place early in the life of the culture and was now proliferating, giving the mosaic appearance in one of the flasks. Both remaining culture flasks showed cells with a 46,XY karyotype.

The findings were discussed with the patient and her husband. A second amniocentesis was performed. Results of this sample are listed in Table 2. The 45,X cell line, which had been in only one flask, was now present in all three.

These findings and the possible implications were discussed with the patient and her husband; they elected to terminate the pregnancy. Termination was achieved at 24 weeks gestation (22 from conception) by intra-amniotic injection of prostaglandins and urea. A phenotypically normal fetus was passed approximately 18 hours later.

Autopsy Findings

Autopsy revealed that the penis and scrotum were normally formed. Two scrotal testes were noted and were normal grossly and histologically. No anatomic abnormalities were noted other than a dilated bladder without anatomic obstruction. Tissue cultures for chromosomes were carried out using thymus, spleen, kidney, and fascia. These results are listed in Table 3. The mosaic pattern observed in the amniotic fluid was also present in the tissues.

Discussion

It is not considered unusual to find an aneuploid cell distributed among the normal cells seen during the microscopic examination. Twenty cells are counted and analyzed before rendering a diagnosis. We find it common for one or two cells not to have the diploid chromosomal pattern. Random loss or gain is an accepted phenomenon and can be explained readily by either a

Table 1. First Sample Results

Flask	Cell Type	No. of Cells
A	46,XY	12
B	46,XY	35
C	45,X	20
C_1	46,XY	2

Table 2. Second Sample Results

Flask	Cell Type	No. of Cells	Percent
A	46,XY	64	84
	45,X	12	16
B	46,XY	13	92
	45,X	1	8
C	46,XY	8	80
	45,X	2	20
Total	46,XY	85	85
	45,X	15	15
		100	

Table 3. Tissue Culture Results

Tissue	X	XY	Total	Percent X
Thymus	4	16	20	20
Spleen	5	15	20	25
Kidney	6	14	20	30
Fascia	0	20	20	0
	15	65	80	18

cultural artifact or the preparational technique. Subsequently, to be considered as a real occurrence, the abnormality should be seen in more than one culture flask with reasonable consistency.

Likewise, it is difficult to make an accurate karyotype-phenotype correlation in cases of mosaicism as seen in amniotic fluid cell culture. We then are faced with the ever-present prenatal dilemma of deciding what is real and what is artifact. In this particular case, what was felt in the beginning to be a cultural artifact was in fact a real representation of the fetus. We can offer no plausible explanation of why the 45,X cells segregated to only one flask when reason would have them evenly dispersed in all flasks. If only a small amount of the 45,X cells were present in the original sample, perhaps they all might have been placed in a single flask. In the second sample, the aneuploid cells were placed more evenly into the separate flasks.

The level of mosaicism found in the second fluid was almost identical to that found when tissue samples were studied. Which tissues were affected was also of interest. The fascia did not appear to have any mosaic cells, whereas the underlying tissues did. Perhaps the explanation for this lies in the origin of these tissues: fascia, being of ectodermal origin not being involved in the divisional error that caused the underlying mesodermal organs to be affected.

Several lessons may be gained from this experience. Study of at least two culture flasks is needed when this method of amniotic fluid analysis is employed. All aneuploid cells should not be viewed as artifact, especially when seen in large numbers. Tissue culture confirmation in various tissue types to help explain the mechanism of mosaicism is always important.

Reference

1. deGrouchy, J. and Turleau, C. *Clinical Atlas of Human Chromosomes*, Second Edition. New York: John Wiley & Sons, 1984.

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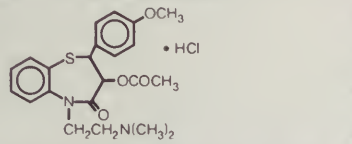
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CLINICAL PHARMACOLOGY

The therapeutic benefits achieved with CARDIZEM are believed to be related to its ability to inhibit the influx of calcium ions during membrane depolarization of cardiac and vascular smooth muscle.

Mechanisms of Action. Although precise mechanisms of its antianginal actions are still being delineated, CARDIZEM is believed to act in the following ways:

1. Angina Due to Coronary Artery Spasm: CARDIZEM has been shown to be a potent dilator of coronary arteries both epicardial and subendocardial. Spontaneous and ergonovine-induced coronary artery spasm are inhibited by CARDIZEM.
2. Exertional Angina: CARDIZEM has been shown to produce increases in exercise tolerance, probably due to its ability to reduce myocardial oxygen demand. This is accomplished via reductions in heart rate and systemic blood pressure at submaximal and maximal exercise work loads.

In animal models, diltiazem interferes with the slow inward (depolarizing) current in excitable tissue. It causes excitation-contraction uncoupling in various myocardial tissues without changes in the configuration of the action potential. Diltiazem produces relaxation of coronary vascular smooth muscle and dilation of both large and small coronary arteries at drug levels which cause little or no negative inotropic effect. The resultant increases in coronary blood flow (epicardial and subendocardial) occur in ischemic and nonischemic models and are accompanied by dose-dependent decreases in systemic blood pressure and decreases in peripheral resistance.

Hemodynamic and Electrophysiologic Effects. Like other calcium antagonists, diltiazem decreases sinoatrial and atrioventricular conduction in isolated tissues and has a negative inotropic effect in isolated preparations. In the intact animal, prolongation of the AH interval can be seen at higher doses.

In man, diltiazem prevents spontaneous and ergonovine-provoked coronary artery spasm. It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure and, in exercise tolerance studies in patients with ischemic heart disease, reduces the heart rate-blood pressure product for any given work load. Studies to date, primarily in patients with good ventricular function, have not revealed evidence of a negative inotropic effect; cardiac output, ejection fraction, and left ventricular end diastolic pressure have not been affected. There are as yet few data on the interaction of diltiazem and beta-blockers. Resting heart rate is usually unchanged or slightly reduced by diltiazem.

Intravenous diltiazem in doses of 20 mg prolongs AH conduction time and AV node functional and effective refractory periods approximately 20%. In a study involving single oral doses of 300 mg of CARDIZEM in six normal volunteers, the average maximum PR prolongation was 14% with no instances of greater than first-degree AV block. Diltiazem-associated prolongation of the AH interval is not more pronounced in patients with first-degree heart block. In patients with sick sinus syndrome, diltiazem significantly prolongs sinus cycle length (up to 50% in some cases).

Chronic oral administration of CARDIZEM in doses of up to 240 mg/day has resulted in small increases in PR interval, but has not usually produced abnormal prolongation. There were, however, three instances of second-degree AV block and one instance of third-degree AV block in a group of 959 chronically treated patients.

Pharmacokinetics and Metabolism. Diltiazem is absorbed from the tablet formulation to about 80% of a reference capsule and is subject to an extensive first-pass effect, giving an absolute bioavailability (compared to intravenous dosing) of about 40%. CARDIZEM undergoes extensive hepatic metabolism in which 2% to 4% of the unchanged drug appears in the urine. In vitro binding studies show CARDIZEM is 70% to 80% bound to plasma proteins. Competitive ligand binding studies have also shown CARDIZEM binding is not altered by therapeutic concentrations of digoxin, hydrochlorothiazide, phenylbutazone, propranolol, salicylic acid, or warfarin. Single oral doses of 30 to 120 mg of CARDIZEM result in detectable plasma levels within 30 to 60 minutes and peak plasma levels two to three hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3.5 hours. Desacetyl diltiazem is also present in the plasma at levels of 10% to 20% of the parent drug and is 25% to 50% as potent a coronary vasodilator as diltiazem. Therapeutic blood levels of CARDIZEM appear to be in the range of 50 to 200 ng/ml. There is a departure from dose-linearity when single doses above 60 mg are given; a 120-mg dose gave blood levels three times that of the 60-mg dose. There is no information about the effect of renal or hepatic impairment on excretion or metabolism of diltiazem.

INDICATIONS AND USAGE

1. **Angina Pectoris Due to Coronary Artery Spasm.** CARDIZEM is indicated in the treatment of angina pectoris due to coronary artery spasm. CARDIZEM has been shown effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (resting angina with ST-segment elevation occurring during attacks).
2. **Chronic Stable Angina (Classic Effort-Associated Angina).** CARDIZEM is indicated in the management of chronic stable angina. CARDIZEM has been effective in controlled trials in reducing angina frequency and increasing exercise tolerance.

There are no controlled studies of the effectiveness of the concomitant use of diltiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities.

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

1. **Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
2. **Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
3. **Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
4. **Acute Hepatic Injury.** In rare instances, patients receiving CARDIZEM have exhibited reversible acute hepatic injury as evidenced by moderate to extreme elevations of liver enzymes. (See PRECAUTIONS and ADVERSE REACTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS).

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vitro bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outweigh its potential risks in this situation.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences, as well as their frequency of presentation, are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%), AV block (1.1%). In addition, the following events were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrence.

Cardiovascular:	Flushing, arrhythmia, hypotension, bradycardia, palpitations, congestive heart failure, syncope.
Nervous System:	Paresthesia, nervousness, somnolence, tremor, insomnia, hallucinations, and amnesia.
Gastrointestinal:	Constipation, dyspepsia, diarrhea, vomiting, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH.
Dermatologic:	Pruritus, petechiae, urticaria, photosensitivity.
Other:	Polyuria, nocturia.

The following additional experiences have been noted:

A patient with Prinzmetal's angina experiencing episodes of vasospastic angina developed periods of transient asymptomatic asystole approximately five hours after receiving a single 60-mg dose of CARDIZEM.

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: erythema multiforme; leukopenia; and extreme elevations of alkaline phosphatase, SGOT, SGPT, LDH, and CPK. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

OVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with oral diltiazem has been limited. Single oral doses of 300 mg of CARDIZEM have been well tolerated by healthy volunteers. In the event of overdosage or exaggerated response, appropriate supportive measures should be employed in addition to gastric lavage. The following measures may be considered:

Bradycardia	Administer atropine (0.60 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.
High-Degree AV Block	Treat as for bradycardia above. Fixed high-degree AV block should be treated with cardiac pacing.
Cardiac Failure	Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics.
Hypotension	Vasopressors (eg, dopamine or levarterenol bitartrate).

Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating physician.

The oral LD_{50}'s in mice and rats range from 415 to 740 mg/kg and from 560 to 810 mg/kg, respectively. The intravenous LD_{50}'s in these species were 60 and 38 mg/kg, respectively. The oral LD_{50} in dogs is considered to be in excess of 50 mg/kg, while lethality was seen in monkeys at 360 mg/kg. The toxic dose in man is not known, but blood levels in excess of 800 ng/ml have not been associated with toxicity.

DOSAGE AND ADMINISTRATION

Exertional Angina Pectoris Due to Atherosclerotic Coronary Artery Disease or Angina Pectoris at Rest Due to Coronary Artery Spasm. Dosage must be adjusted to each patient's needs. Starting with 30 mg four times daily, before meals and at bedtime, dosage should be increased gradually (given in divided doses three or four times daily) at one- to two-day intervals until optimum response is obtained. Although individual patients may respond to any dosage level, the average optimum dosage range appears to be 180 to 240 mg/day. There are no available data concerning dosage requirements in patients with impaired renal or hepatic function. If the drug must be used in such patients, titration should be carried out with particular caution.

Concomitant Use With Other Antianginal Agents:

1. **Sublingual NTG** may be taken as required to abort acute anginal attacks during CARDIZEM therapy.
2. **Prophylactic Nitrate Therapy**—CARDIZEM may be safely coadministered with short- and long-acting nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.
3. **Beta-blockers.** (See WARNINGS and PRECAUTIONS.)

HOW SUPPLIED

Cardizem 30-mg tablets are supplied in bottles of 100 (NDC 0088-1771-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1771-49). Each green tablet is engraved with MARION on one side and 1771 engraved on the other. CARDIZEM 60-mg scored tablets are supplied in bottles of 100 (NDC 0088-1772-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1772-49). Each yellow tablet is engraved with MARION on one side and 1772 on the other.

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Recent Advances in the Early Diagnosis of Osteoporosis: A Review

ROBERT D. KATZ MD

Osteoporosis is a pervasive disease in the general population that has staggering costs to society in terms of morbidity, mortality, and economics. However, various regimens are effective in maintaining or increasing bone mineral content and in decreasing the risk of fractures.

Several methods are available to determine the bone mineral density of the spine, allowing identification of patients at high risk for fractures and for follow-up of adequacy of treatment. Based on its accuracy, reproducibility, and low radiation dose, dual photon absorptiometry now is seen as the optimal technique for determination of bone mineral density.

Dr. Katz is Assistant Professor of Radiology at the Johns Hopkins University School of Medicine, Baltimore, MD, and practices in Northwest Baltimore. Reprints available from the author: 122 Slade Ave., Suite 300, Baltimore, MD 21208.

Osteoporosis, the condition of low bone mineral density resulting in fracture or increased risk of fracture, has reached epidemic proportions in the United States. In 1983, of an estimated 300,000 hip fractures in the U.S., the vast majority (75 percent) could be attributed to osteoporosis. The estimated financial costs for just the acute care of these hip fractures is approximately $3 billion (approximately 1 percent of the health care budget in the country). The estimated mortality rate from hip fractures is 10 to 20 percent. Approximately 25 percent of white women over age 65 have at least one spontaneous compression fracture of the spine, another manifestation of osteoporosis.[1,2]

Myths About Osteoporosis

A number of myths about osteoporosis exist, including:

- Osteoporosis is an inevitable consequence of aging
- Once osteoporosis develops, it is not useful to treat it
- There is no benefit in beginning treatment years after menopause
- Treatment for osteoporosis must be continued indefinitely for lasting beneficial effects
- There is no way to distinguish patients at greater risk for fractures from those at lower risk
- There is no way to monitor response to therapy

This article refutes these myths and demonstrates a major recent advance in the early diagnosis of osteoporosis, dual photon absorptiometry, which allows the accurate and reproducible quantification of bone density in the spine.

Myth 1: Osteoporosis is an inevitable consequence of aging Osteoporosis has been considered an inevitable consequence of aging. However, numerous studies have shown that treatment with multiple therapeutic regimens (including estrogen,[3–9] progestagens,[10] calcium,[11,12] fluoride,[13,14] thiazides,[15,16] and even exercise[17,18]) not only decreases bone loss but also actually increases bone mineral density. Studies also have shown that treatment decreases the frequency of fractures associated with osteoporosis.[19–25] Therefore, although there is normal age-related bone loss that is accelerated at menopause,[26–28] appropriate treatment provided early in the course of demineralization can prevent osteoporosis.

Myth 2: Once osteoporosis has developed, it is not useful to treat it A major study from the Mayo Clinic published in the *New England Journal of Medicine*[29] showed that treatment is effective in preventing subsequent fractures in patients who have osteoporosis manifested by at least one compression fracture of the spine. This study showed that treatment with calcium alone decreased the subsequent vertebral fracture rate by approximately 50 percent compared to the untreated group. Treatment with estrogen in addition to calcium decreased the subsequent fracture rate by an additional 50 percent; treatment with fluoride (40–60 mg per day) in addition to the calcium-estrogen regimen decreased the subsequent fracture rate an additional 50 percent, so that the subsequent fracture rate was only one-eighth that of untreated patients. This study clearly demonstrated that even though significant osteoporosis had developed, it was still useful to treat these patients since treatment greatly decreased the subsequent fracture rate. Data from this study are shown in Figure 1, next page.

Myth 3: There is no benefit in beginning treatment years after menopause Meema *et al.*[30] and Lindsay[31] have shown, using quantitative techniques, that bone mineral density may be increased with estrogen treatment begun as late as fifteen years after menopause. Thus, treatment is effective even if begun years after menopause.

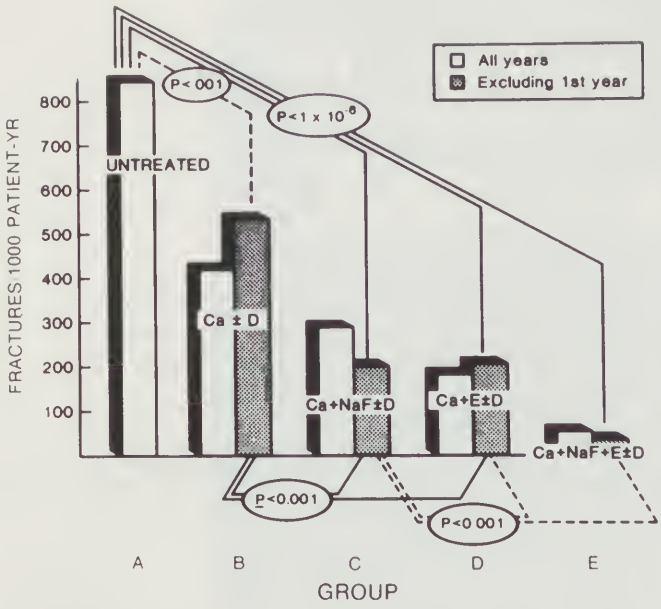


Figure 1. Comparison of fracture incidence in untreated patients and patients receiving various combinations of calcium (Ca), sodium fluoride (NaF), estrogen, (E), and vitamin D (D).

The fracture rate was reduced in all treatment groups. The components of fluoride (after one year of treatment) and estrogen independently reduced the fracture rate from that observed with calcium alone, and a combination of all three agents was maximally effective.

(Reprinted with permission from Riggs, B.L.; Seeman, E; Hodgson, S.F., *et al.* "Effects of Fluoride/Calcium Regimen on Vertebral Fracture Occurrence in Post-menopausal Osteoporosis. Comparison with Conventional Therapy." *N Engl J Med* 306 (1982): 446–450.)



Figure 2.

Myth 4: Treatment of osteoporosis must be continued indefinitely for lasting beneficial effects Christiansen *et al.*[22] have shown conclusively that withdrawal of treatment for osteoporosis does not result in increased rate of bone loss after withdrawal of treatment. Instead, the rate of bone loss is the same as though the patient had never been treated. Therefore, the benefits (increased bone density) that accrue during the period of treatment result in the patient's bone density being greater than if she had never been treated at all. The beneficial effects of even temporary treatment persist after treatment is discontinued.

Myth 5: There is no way to distinguish patients at greater risk for fracture from those at lower risk It has been known for many years that standard bone radiographs do not show bone loss until 30 to 50 percent of the bone is lost and that radiographs are not accurate enough to quantitate bone loss.[33,34]

New techniques provide accurate and reproducible quantification of bone density, allowing identification of patients at high risk for fracture before fractures occur as well as monitoring the effects of therapy. The best technique available, dual photon absorptiometry, allows the accurate (compared to ashed vertebral specimen analysis and total body calcium analysis) and reproducible (2 to 3 percent error)[35–40] determination of the bone mineral density of the lumbar spine. Measuring the lumbar spine is important since it is composed of predominantly (66 percent) trabecular bone, which is metabolically more active than cortical bone and therefore more representative of the active processes of demineralization and remineralization. In addition, decreased lumbar spine bone mineral density is correlated with increased risk of fractures of the spine[41] and intertrochanteric region of the femur.[42]

Dual Photon Absorptiometry Technique

In this technique, the patient is positioned comfortably on a table. A photon source (^{153}gadolinium) is located below the table and a detector is located above the table. This instrument is interfaced to a computer, through which the instrument is controlled and the data processed and analyzed (see Figure 2).

When the scan is started, the gadolinium source beneath the patient emits photons of two different energies (hence the name "dual photon") (see Figure 3). Some of the photons are absorbed by the patient (hence the term "absorptiometry"). The photons that are not absorbed pass through the patient and are detected by the detector above. This allows the determination of bone density in the spine, since a denser

spine absorbs more photons. The use of two different energy photons is essential to allow the computer to differentiate absorption by bone from absorption by soft tissue. The source scans the lumbar spine from L1 through L4.

Dual Photon Absorptiometry Clinical Data

Using daily calibration techniques with standards of known density, dual photon absorptiometry provides accurate and reproducible measurement of the bone mineral density in grams per square centimeter.

The absolute measurement in grams per square centimeter is compared to age- and weight-matched controls and to the bone mineral density measurements of patients with spinal compression fractures studied at the Mayo Clinic and The University of Wisconsin. Investigators at the Mayo Clinic have shown that 90 percent of women with spinal compression fractures have lumbar spine bone mineral density values (determined from L1 through L4) less than 0.965 grams per square centimeter. No one with bone mineral density greater than 1.4 grams per square centimeter had spinal compression fractures.[43] The data from their patients with compression fractures compared to age-matched controls are demonstrated in Figure 4.

Data from the Mayo Clinic also indicate that a bone mineral density of less than 1.2 grams per square centimeter is associated with a spinal fracture risk nearly 70 times greater than if the value is more than 1.2; if the bone mineral density is less than 1.0, fracture risk is approximately 250 times greater. The risk of fracture increases even more with lower bone mineral densities (see Table, next page).

An example of an asymptomatic woman identified as being at risk for fracture is shown in Figure 5, next page.

Myth 6: There is no way to monitor response to therapy Dual photon absorptiometry has given very reproducible measurements of bone mineral density, the error of reproducibility being 2 to 3 percent.[45] Therefore, on repeated measurements on the same patient, a difference in bone mineral density more than 2 to 3 percent can be considered meaningful. Since decreases in bone mineral density in patients without treatment often exceed 2 to 3 percent per year, and since increases in bone mineral density in patients receiving treatment often exceed 2 to 3 percent per year, repeated measurements at yearly intervals are valuable. Dual photon-absorptiometry allows monitoring of the effectiveness of therapy.

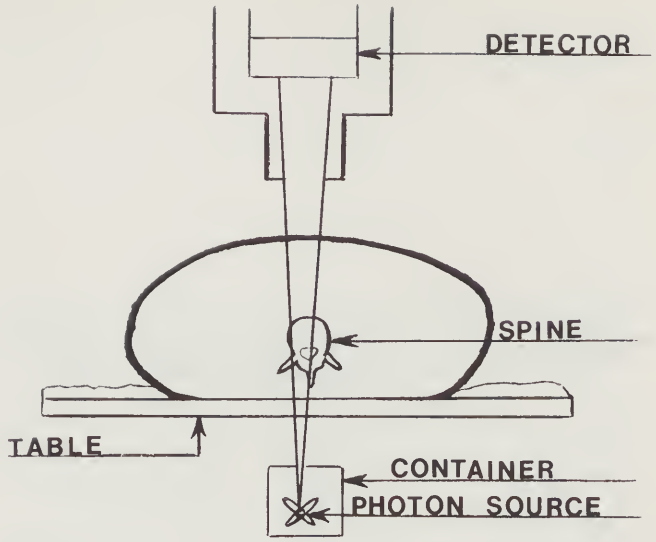


Figure 3.

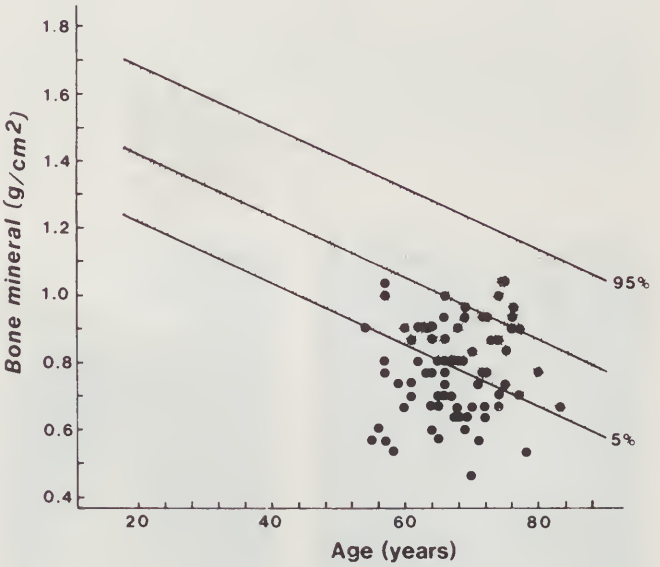


Figure 4. Individual values for bone mineral density of the lumbar spine in women with osteoporosis and one or more vertebral compression fractures (each dot represents a patient). Center line denotes age regression for normal women, and upper and lower lines represent 90 percent confidence limits.

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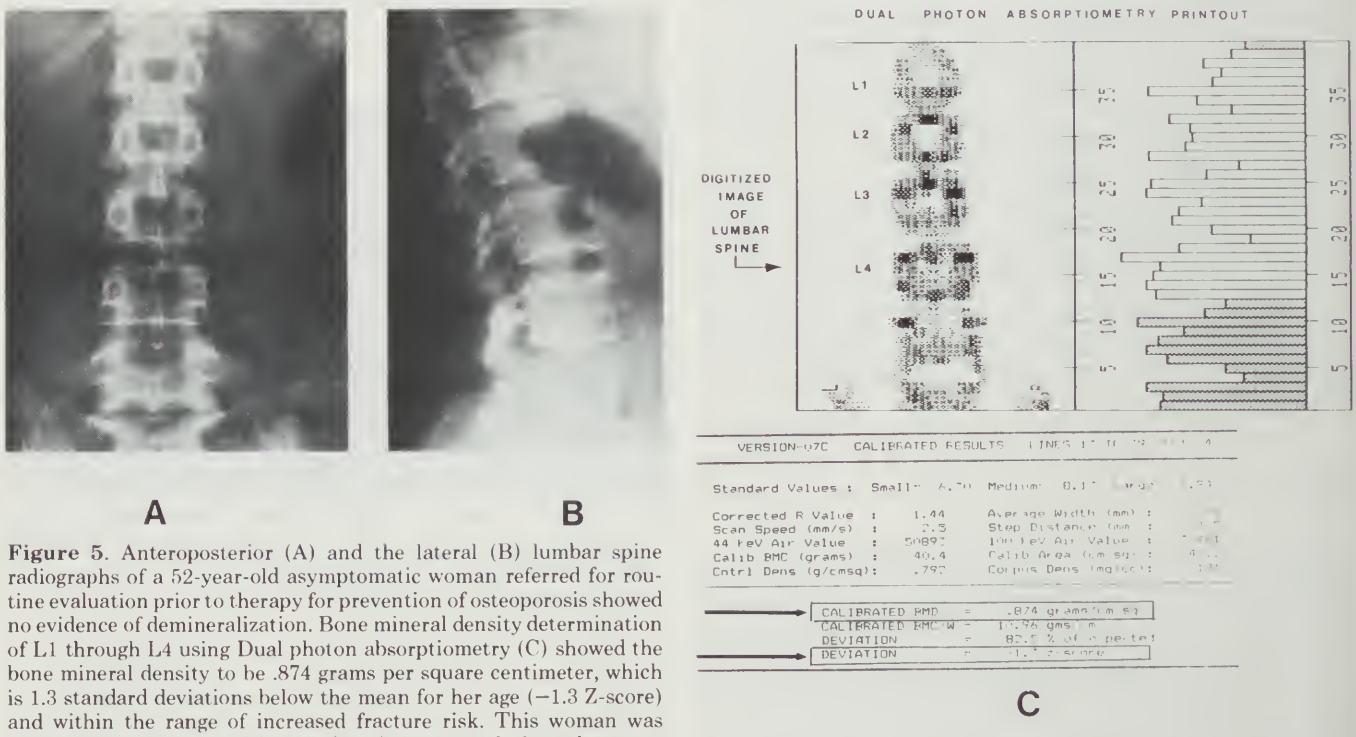
Table. Prevalence and Incidence of Fractures at Different Bone Mineral Densities among Rochester, Minnesota Women

Bone Mineral Density (gms per cm^2)	Lumbar Spine Fractures (per 100 women)	Hip Fractures (per 1,000 patient-years)	
		Neck	Trochanter
≥1.40	0	0	0
1.20–1.39	0.1	0	0
1.00–1.19	6.8	0.2	0.1
0.80–0.99	26.1	2.0	0.8
0.60–0.79	47.5	6.5	5.3
<0.60	48.8	8.8	17.6

Source: Melton, L.I.; Wahner, H.W.; Richelson, L.S.; *et al.* "Bone-density-specific Fracture Risk: A Population-based study of the Relationship between Osteoporosis and Vertebral Fractures." *J Nucl Med* 26 (1985); P24 (Ast).

Other Techniques

Single photon absorptiometry provides bone mineral density measurements using photons of a single energy emitted from an ^{125}iodine source. This technique cannot differentiate between absorption by bone and absorption by soft tissue, since only single energy photons are employed. Therefore, the technique is limited to measuring bone density in the appendicular bones (usually the radius and ulna) where there is only minimal soft tissue. These bones are composed primarily of cortical bone, which is relatively inactive metabolically. Although low radius bone mineral content indicates a high probability of low spinal bone mineral, a normal value does not exclude spinal osteoporosis. It is doubtful that forearm bone mineral density can be used to reliably diagnose and quantify early bone loss in osteoporosis.[46]



A B C

Figure 5. Anteroposterior (A) and the lateral (B) lumbar spine radiographs of a 52-year-old asymptomatic woman referred for routine evaluation prior to therapy for prevention of osteoporosis showed no evidence of demineralization. Bone mineral density determination of L1 through L4 using Dual photon absorptiometry (C) showed the bone mineral density to be .874 grams per square centimeter, which is 1.3 standard deviations below the mean for her age (−1.3 Z-score) and within the range of increased fracture risk. This woman was therefore noninvasively identified as being at risk for subsequent fractures and was therefore a candidate for aggressive treatment and careful follow-up.

Quantitative computerized tomography, which has been used for the determination of bone mineral density in the spine, has several major disadvantages including (1) a radiation dose up to 100 times greater than dual photon absorptiometry, (2) lower accuracy (especially in patients with fatty bone marrow), and (3) poorer reproducibility.[47-52] Based on these considerations, dual photon absorptiometry is considered the superior technique.

Conditions in Which Osteoporosis May Occur

Osteoporosis occurs in a number of different conditions. Decreased estrogen levels are thought to be responsible for postmenopausal osteoporosis and for osteoporosis following oophorectomy.[53] Women athletes[54] and women with anorexia nervosa[55] may become osteoporotic, probably related to their becoming amenorrheic. Dual photon absorptiometry can identify those women who are demineralized on the basis of their menopausal status, prior oophorectomy, athletic activity, or anorexia, and provides a baseline for comparison with subsequent determinations.

Patients with other metabolic conditions associated with osteoporosis also can benefit from bone mineral density determination. Approximately half the patients receiving long-term corticosteroid therapy develop significant osteoporosis.[56] Dual photon absorptiometry can identify those patients who have low bone mineral density to start with or who are rapid bone losers due to their steroid therapy, so that specific therapy (such as calcium, vitamin D, and hydrochlorthiazide) can be instituted.

Patients with hyperparathyroidism can be evaluated with dual photon absorptiometry. If there is significant demineralization, the decision whether to perform parathyroid surgery may be affected.

Patients with diabetes may have a painful osteopathy associated with demineralization.[57] Dual photon absorptiometry can identify those patients.

Clinical Utility

Accurate reproducible bone mineral density using dual photon absorptiometry is useful in a number of situations. For example, a menopausal patient without significant demineralization on her initial study may be started on a basic regimen such as calcium, without estrogen. If after a year of treatment the bone mineral density decreases or shows no improvement additional treatment (such as with estrogen and a progestagen) can be started. If the bone mineral density increases after one year of treatment with calcium alone, calcium may be continued without starting estrogen. If the bone mineral density falls significantly, additional therapy probably is warranted.

If, on the other hand, a woman has a very low bone mineral density on the initial determination (for example, less than .900 grams per square centimeter), treatment with calcium and estrogen would be a reasonable initial therapy. If the bone mineral density does not improve with that regimen, fluoride therapy (in a dose of 40–60 mgs per day) can then be considered. (Fluoride should not be used routinely because of the high incidence of gastrointestinal and rheumatologic side effects.)

Dual photon absorptiometry can identify the patient at high risk for fracture prior to the initiation of therapy and can monitor the response to therapy. If the patient does not respond to therapy, the therapeutic regimen may be modified. If the patient does respond, the patient can be so informed, increasing the likelihood of patient compliance.

Who benefits from bone mineral density determination using dual photon absorptiometry?

1. Women being considered for therapy for osteoporosis at the time of menopause or following oophorectomy
2. Women who are amenorrheic due to exercise or anorexia nervosa
3. Patients receiving chronic corticosteroid therapy
4. Patients who have suspected hyperparathyroidism
5. Patients with diabetes in whom osteopathy is considered because of bone pain
6. Patients whose radiographs suggest osteoporosis, for confirmation and precise quantification
7. All patients whose bone density can be demonstrated to increase following treatment, since this demonstration should enhance patient compliance.

Disadvantages of not measuring bone mineral density

1. High-risk patients may not be identified until after fractures occur.
2. Patients who don't respond to conventional treatment will not be identified, and their treatment may not be modified appropriately.

Conclusion

Now, for the first time, individual patients who have significant osteoporosis and/or rapid bone loss and, therefore, are at greater risk for subsequent osteoporotic fractures can be identified initially and with fol-

low-up studies. Likewise, the adequacy of treatment regimens (such as calcium, estrogen, progestagens, fluoride, exercise) can be assessed in individual patients, providing a basis for therapeutic decisions *before* advanced disease ensues. This capability provides the clinician with a powerful new tool to evaluate and monitor the many forms of osteroporosis and its treatments.

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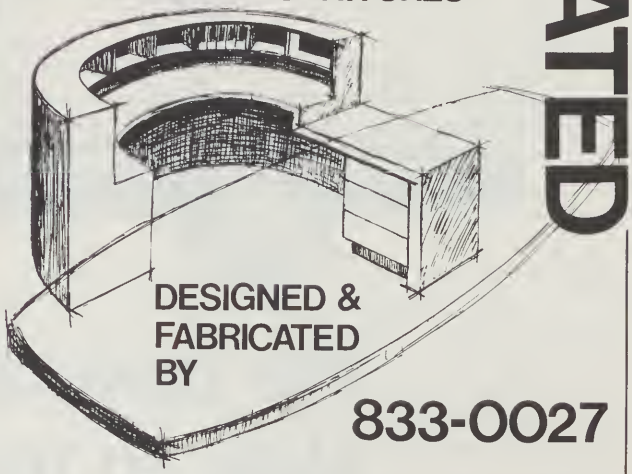
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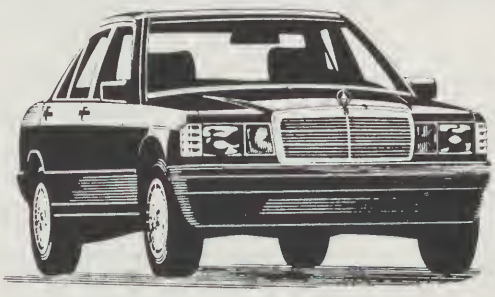


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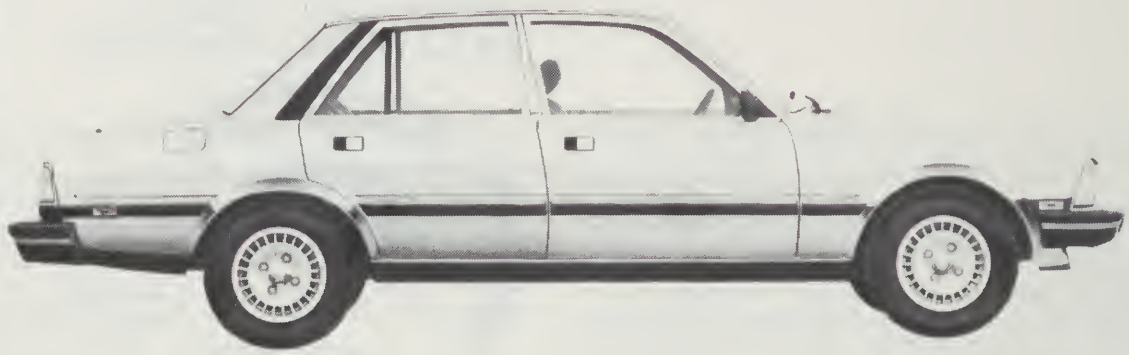


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Smoking: The Number One Health Problem

EDWARD N. BRANDT, JR., MD

Physicians have a responsibility to prevent illness, disability, and premature death. The number one cause of all of these is cigarette smoking. It accounts for about 340,000 deaths each year and is the largest single killer in our society. Virtually all these deaths are preventable. Physicians cannot depend on government or other agencies to get patients to stop smoking: therapeutic intervention is possible and it works.

Dr. Brandt is Chancellor of the University of Maryland at Baltimore, 520 West Lombard Street, Baltimore, MD 21201.

Cigarettes were introduced in the United States around 1915. Prior to that, tobacco was consumed mostly as cigars, pipe tobacco, chewing tobacco, and snuff. Public health workers initially welcomed cigarettes because tuberculosis was a significant health problem, and they believed reducing spitting in public would be an important advance against that disease.

After 1915, cigarette smoking literally took off. Nicotine is an addictive drug, and cigarette smokers are addicted: 1980 consumption in this country totaled 640 billion cigarettes or about half a package for every man, woman, and child. The World Health Organization is considering reclassifying cigarette smoking as an addictive disorder.

Lung cancer is a relatively new disease. In 1930 about 3,000 lung cancer deaths were recorded; by 1984 the number of deaths had risen to 120,000. Curves for cigarette smoking and lung cancer deaths have been increasing in parallel.

Health Risks

A smoker is ten times more likely to die of lung cancer than a nonsmoker. However, lung cancer is only one of many cancers caused by cigarette smoking. Others include carcinomas of the larynx, oral cavity, and esophagus. There is a relationship between smoking and cancers of the bladder, pancreas, and kidneys. Approximately 30 percent of all cancer deaths (or 130,000 deaths annually) are due to cigarette smoking. Lung cancer has surpassed breast cancer as the leading cause of cancer death in women.

Cancer is only one health problem posed by cigarette smoking. For example, cigarette smoking has a significant and adverse effect on the well-being of the fetus and the baby's development. Spontaneous abortion, prematurity, and low birth weight as well as fetal and infant deaths occur more frequently when the pregnant woman smokes.

Coronary artery disease also is due, in large part, to cigarette smoking. Smoking accounts for approximately 170,000 deaths annually from coronary artery disease. Women face a special risk: those who smoke and use oral contraceptives have ten times more risk of coronary artery disease.

Cigarette smoking also leads to marked disability. The most classic example is chronic obstructive lung disease, which is a debilitating, wasting disease. Through its impact on the pulmonary system, cigarette smoking can complicate other chronic diseases.

One of the more controversial aspects of the smoking problem is the role of additives in cigarettes. Tobacco contains a number of organ-specific carcinogens: nitrosamines, nitrosopiperidine, and many others. These are released by the burning of tobacco, then are inhaled and absorbed into the bloodstream. Low tar and low nicotine cigarettes are developed by reducing the amount of tobacco and/or increasing aeration of the tobacco while burning. Both reduce the taste of cigarettes; hence, additives have been selected to give taste to cigarette smoke. The most common additive is menthol. The exact additives used is a competitive secret guarded zealously by manufacturers. Relatively few toxicological studies of substances burned at high temperatures have been done; thus, it is not possible at present to determine whether additives increase the health risks of cigarette smoking.

A second controversy involves what is known as passive smoking. Is there a risk to nonsmokers from being near smokers? The answer is not yet conclusive, but it is clear that persons in a room with smokers inhale many of the same carcinogenic elements smokers absorb. Studies indicate that flight attendants working in a plane's smoking section for a three- to four-hour flight showed blood concentration of various substances equivalent to smoking one cigarette. Children who live with one or more smoking parent have a far greater incidence of pulmonary infections and ear infections than do children who do not live in such an environment. Passive smoking *is* a problem that *does have* a negative impact on nonsmokers.

Government Regulations

What can be done about this problem? Many people advocate government intervention. Tobacco in the United States is regulated by Congress and several nonhealth agencies including the Federal Trade Commission and the Civil Aeronautics Board. The two primary forms of government regulations are labeling and advertising; neither limit access to tobacco. Banning cigarettes would not end cigarette smoking but probably would increase smuggling of cigarettes.

Many people advocate higher taxes as a disincentive to consumption. Cigarette tax income can be a significant funding source for government, leading to government dependence on cigarette sales. There is no question that the price of cigarettes influences consumption: the higher the price, the lower the consumption. Furthermore, increasing taxes increases prices. The government must be cautious about the balance between the taxes it charges and its dependence on tax revenue. During the worldwide recession a couple of years ago, public health officials in Finland were instructed to ease their antismoking efforts because it reduced government income at a time when the government was in fiscal trouble.

However, cigarette smoking does have a dramatic negative effect on the American economy. In 1980, studies led to the conclusion that direct medical costs from cigarette smoking amounted to $16.1 billion. Indirect costs including disability, premature death, and loss of work time amounted to an additional $26.1 billion.

Therapeutic Intervention

There are specific steps physicians can take to assist in this problem. The most obvious is to help patients quit smoking. It is easy to say that to quit smoking requires only willpower. However, cessation of cigarette smoking leads to true, measurable, physiological withdrawal symptoms. These symptoms are unpleasant and associated with great anxiety.

Cigarette smoking tends to be somewhat ritualistic. That is, smokers tend to associate pleasurable aspects of smoking with specific times in their lives: after eating, during periods of anxiety and stress, and while working, especially on a job that requires concentration. Hence it is necessary that withdrawal symptoms be treated and that treatment be administered at those times the person has realized the greatest pleasure.

For addiction to other chemicals, such as heroin, it has been possible to find specific receptor sites in the brain and, potentially, to develop ways to interfere with, or block, those receptor sites. No similar receptor sites have been identified for nicotine, but work is progressing.

The most promising form of therapeutic intervention is provision of nicotine at those times associated with greatest pleasure followed by gradual but steady reduction in the amount of nicotine given. That is the basic principle underlying Bantron(R) and a nicotine chewing gum, Nicorette(R); other substances with actions similar to nicotine, such as lobelline, also are useful. Nicotine is a dangerous drug: Nicorette(R) is available only by prescription and under a physician's supervision. Directions on these products emphasize administration at times largely set by the individual based on his/her reaction to cigarettes. Evidence is accumulating that this strategy works well. In particular, studies of Nicorette(R) chewing gum are very impressive.

A second step in cessation of cigarette smoking is support. Stopping smoking must be accompanied by positive reinforcement by the family, co-workers, and other persons associated with the smoker. Peer pressure and peer reinforcement are important elements as the person undergoes withdrawal and a marked change in behavior. Hence, it is important that the family understand what will happen and that they give support rather than condemnation.

In addition, positive aspects should be stressed. For example, as time passes chronic nasal and laryngeal irritation will subside, taste will be enhanced, and exercise tolerance will improve.

Local laws that restrict smoking are helpful. If extra effort is required to smoke (such as having to go to a designated smoking area or outside) then the chances a person will yield to physiological cravings are reduced.

Many people fear gaining weight during this period because they tend to substitute food for cigarettes. This threat can be relieved by encouraging them to chew gum and consume low calorie foods, such as raw vegetables, rather than eat sweets. Another positive aspect of stopping smoking is saving money. Putting the price of a package of cigarettes into a container as often as it would have been spent will reinforce this fact.

Since cigarette smoking is the primary cause of illness, disability, and premature death, smoking should be discouraged. Physicians have a responsibility to apply their efforts to getting people to stop smoking. Therapeutic intervention is possible, and it does work.



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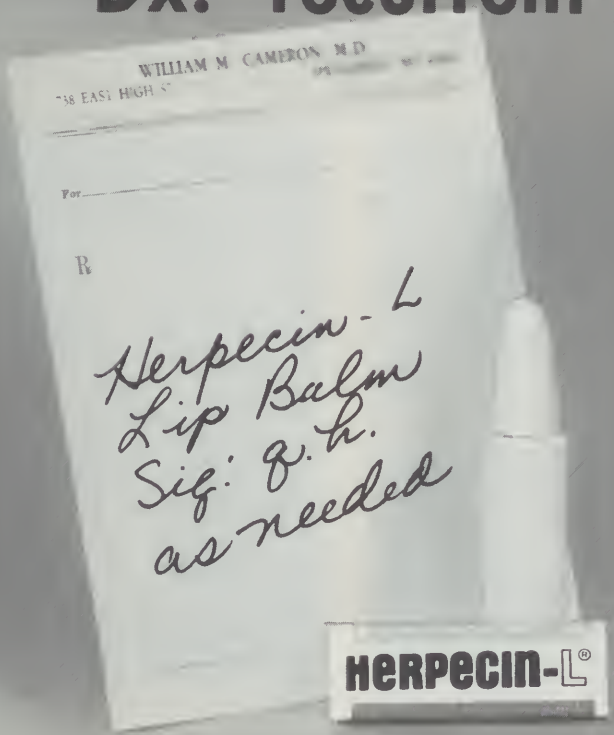
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Supporting Maryland Physicians: The Med-Chi Staff

EVE LEHMAN

When 1211 Cathedral Street became home of the Maryland medical society in 1909, two full-time and three part-time employees carried out the daily activities of the Faculty. Seventy-five years later the Faculty staff numbers thirty-five full-time and four part-time employees performing a diverse and complex duty: providing support for Maryland physicians in their daily practice, continuing education, relationship with the public, and pursuit and achievement of goals for the future of medical care. In number and variety of functions, staff growth reflects the needs of physician members.

Each physician member of the Faculty probably has spoken with at least one member of the Faculty staff during his/her membership. Correspondence, the *Maryland Medical Journal*, meeting agendas, legislative newsletters, and many other staff products arrive in physicians' offices regularly. If a member has a question about medical records, an advertising request or letter to the Editor for the *Journal*, a concern about legislative goings-on in Annapolis, a reference question for a scientific paper (the list could go on and on), who should be called?

Listing every task and responsibility of each of the Faculty staff would be a formidable undertaking. Responsibilities overlap; the staff cooperates to meet deadlines and to answer difficult requests from Faculty members and the public. Even John Sargeant has stuffed an occasional envelope when approaching deadlines and heavy work loads demand team efforts. Thus, the following introduction is intended to familiarize physicians with the Faculty Staff and their general functions rather than to present a complete report of every duty they perform.

• • •

John Sargeant has served the Faculty as Executive Director since 1958. He is executive and general manager of Faculty affairs and represents the Faculty at the national as well as state levels. Sargeant oversees employment and management of personnel. He works closely with staff in carrying out the daily activities of the Faculty. Staff representatives to Med-Chi committees seek Sargeant's guidance in addressing concerns that require consideration by Council or communication with state officials. Questions from physicians and the public often are addressed to Sargeant, and he refers many of these to the staff. Questions concerning Faculty policy should be directed to Sargeant.

Meetings of the Council, House of Delegates, Executive Committee, and many other of Med-Chi's committees are attended by Sargeant. During the legislative session, he is in Annapolis almost daily to lobby for Faculty concerns. Together with Med-Chi lobbyists Elza Davis and Judith Wood, Esquire, he reviews and drafts legislation.

To keep members informed of Faculty activities, Sargeant writes a monthly Executive Director's Newsletter for publication in the *Maryland Medical Journal.*

Lois Spears, Secretary and Assistant to the Executive Director, attends meetings of the Executive Committee, Council, House of Delegates, Bylaws Committee, and Reference Committee. She is involved in planning, scheduling, and coordinating meetings, materials, and correspondence for these groups. With the Bylaws



Sargeant



Spears



Murray

Committee, Spears prepares the Faculty *Bylaws* for publication twice yearly; she oversees the publication of the Faculty *Handbook* annually. Secretarial and administrative duties for the Executive Director and the Faculty officers are performed by Spears, and she maintains close communication with each of the Faculty officers. She is available to answer physicians' inquiries and/or direct their concerns to the appropriate Faculty staff or committee.

Assistant Executive Director Michael Murray reviews and investigates specific problems between physicians and between physicians and patients in cooperation with the Physician-Patient Relations Committee. Murray executes the administrative work of the Committee and answers daily phone calls and correspondence directed to the Committee. He is staff administrator for the Liaison Committee with Department of Health and Mental Hygiene on Medicaid and Medical Assistance Programs and is Med-Chi's staff representative to Maryland Health Care Coalition, a liaison with private industry. Murray fields questions on everything from medical socioeconomics to geriatrics. Questions from news media concerning Med-Chi are directed to Murray.

Donna Boling, Administrative Secretary, supports Murray in administrative responsibilities for each of the committees he staffs. She listens to patient complaints, counsels, and refers callers to an appropriate organization if the Faculty is unable to address a particular concern. Boling is staff representative to the Committee on Long-Term Care.

Connie Townsend, Assistant to the Executive Director, has held a variety of responsibilities during her tenure with the Faculty. She currently staffs and performs administrative duties for the Peer Review Committee, Committee on Physician Rehabilitation, Committee on Drugs, Utilization and Quality Control Professional Review Organization (UQCPRO), MMPAC, and the Maryland Delegation to the AMA. In her capacity as staff representative to the Peer Review Committee and Committee on Physician Rehabilitation, she acts as Med-Chi's liaison with the Commission on Medical Discipline. She answers miscellaneous inquiries from physicians and the public and specializes in answering or referring to the appropriate source questions that baffle other staff. Townsend provides administrative support to the Executive Director.

Robert White recently joined the Faculty as Coordinator for the Committee on Physician Rehabilitation. White is a Certified Alcoholism Counselor and has a master's degree in psychology. He works with the Committee to verify reports concerning impaired physicians, and he coordinates intervention. White sets up contact teams, and follows up on each case the Committee reviews.

Cindy Keefe is Executive Assistant to Connie Townsend. She performs administrative and secretarial duties for the Peer Review Committee, Committee on Physician Rehabilitation, Committee on Drugs, MMPAC, UQCPRO, and the Committee on Alcoholism. She coordinates the Physicians' Placement Service, a clearinghouse of information for physicians relocating to Maryland and for group practices and hospitals seeking physicians. Keefe is responsible for the



Boling



Townsend



White



Keefe

maintenance of most office machinery used by Faculty staff.

Kathy Krizan is Executive Secretary to the Med-Chi Auxiliary and to the Student and Resident Societies. She coordinates and performs administrative duties for the Auxiliary's 1,400 members and for the activities of the Student and Resident Societies. Krizan is responsible for arranging the physician defense (malpractice) panels that meet regularly at Med-Chi and staffs the Committee on Preventive Medicine and Public Health.

Kathy Smith serves as Executive Assistant to the Committee on Emergency Medical Services, the Committee on Medicine and Religion, the Occupational Health Committee, and the CME Review Committee. She also is Administrative Secretary for the American Academy of Psychiatry and Law and the American Board of Forensic Psychiatry, whose main offices are in the Med-Chi Faculty building through a special contract with Med-Chi. She handles correspondence, maintains records, and coordinates activities for the meetings of each committee and organization. Mary Frances Neukam is Smith's assistant and provides administrative and secretarial support. Neukam is Chapter Administrator for the Maryland Chapter of the American Academy of Pediatrics, which also has a special contract with Med-Chi.



Krizan



Smith



Neukam

Legal Counsel

Judith Wood, in-house counsel since 1983, reviews legislation, drafts legislation, and assesses the possible legal implications of bills in the House and Senate. She acts as Med-Chi's liaison with the State's Attorney General's Office.

Wood works closely with the Committee on Professional Ethics to make sure that ethical statements reviewed or written by the Committee are consistent with other ethical obligations and correspond with the law. She is Executive Coordinator for the Medicolegal Committee, which offers physicians an opportunity to resolve their disputes with attorneys through binding arbitration if the parties agree to submit to the process. Wood is working to recruit representatives to the Committee on Hospital Medical Staffs from each of the hospitals in Maryland. She is available to answer questions and/or attend the meetings of other Med-Chi committees on request.

In addition to that roster of responsibilities, Wood reviews contracts, responds to phone calls and letters concerning ethical and medicolegal questions, attends meetings of the House of Delegates and Council, and scrutinizes Faculty policy for implications of which the Faculty should be aware. Physician members may call for informal, quick advice; however, involved questions and requests for formal opinions should be submitted in writing.

In November 1984 the *Compendium of Laws, Regulations, Opinions and Policies Governing the Practice of Medicine in Maryland* was published after extensive revision and update by Judith Wood and Elza Davis and approval by the Attorney General's office. This publication is available to physician members through Med-Chi's legal department.

Eve Lehman provides administrative and secretarial support to legal counsel and staffs the Committee on Emotional Health. With the Committee she coordinates "Today's Psychiatry," a monthly feature debuting in this issue.

Communications

Communications Director Elza Davis is one of Med-Chi's three lobbyists. She staffs the Faculty's Legislative Committee. Davis monitors all legislation being considered in Annapolis and chooses bills of interest to the Faculty. She works closely with in-house counsel Judith Wood and Executive Director John Sargeant in preparing testimony and drafting legislation. Davis is available to answer physician's questions about Faculty action on health care legislation and on the status of bills before the House and Senate. She attends meetings of the Faculty Council, House of Delegates, and Public Relations Committee. She is President of the Maryland Society of Association Executives.

Diane Sakwa, Public Relations/Legislative Secretary, assists Davis in a wide variety of efforts. Davis and Sakwa are busiest during the legislative session, when Davis's daily trips to Annapolis add a sense of urgency to every aspect of their work. Sakwa sends out a weekly legislative newsletter and *Assemblyman* supplement to keep Faculty members updated on legisla-



Wood



Davis



Sakwa

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In her capacity as Public Relations Coordinator, Nina Casey staffs the Public Relations Committee. Together with the Committee Casey wrote the ambitious public relations campaign for 1985–86, which has been approved by the Council. Casey is now responsible for implementing the 1985–86 plan. Casey also coordinates and writes for "Inside Med-Chi," a column appearing monthly in *MMJ*, and supervises script development for Tel-Med, a statewide medical information program coordinated by Elza Davis.

Maryland Medical Journal

The *Maryland Medical Journal* advances through all phases of development in the offices of Ann Wintriss, Managing Editor. Manuscripts are received and directed to the Editorial Board for review; Wintriss corresponds with authors; classified advertisement copy is received; monthly features are coordinated and edited; manuscripts accepted for publication by the Editorial Board return to Wintriss for copy editing; scheduling and planning decisions are made for each issue; text and advertisements are organized for layout; galleys are proofread; close communication with the printer and the advertising agency is maintained; and covers and graphics are developed. Adapting *MMJ* style to enhance readability and choosing cover material that encourages readers to look inside each issue are two of many ways Wintriss shapes the *MMJ*. She has written several articles for *MMJ* and interviews the incoming Faculty president for the August issue each year. Wintriss is assisted with production by Eve Lehman.



Casey



Wintriss



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Scientific Programs

The Faculty staff are probably most visible to physician members at Med-Chi's Annual and Semiannual Meetings. Mary McGibbon, Director of Convention Services, and M'Lou Schram, Assistant Director, plan both meetings in cooperation with the Committee on Scientific Activity.

The Annual and Semiannual Meetings may come around only once a year, but these meetings are on the minds of McGibbon and Schram every day. Planning for each meeting is a year-long process: from letters coordinating speakers for programs, to the booklet listing the program schedule, ending with thank-you letters after the meeting. Although the Committee on Scientific Activity makes decisions regarding scientific programs, follow-through rests entirely on McGibbon and Schram. In addition to scheduling and organizing the scientific programs, they coordinate exhibit booths, travel arrangements, reservations for special functions, and Faculty staff assignments during the meetings.

McGibbon and Schram also plan several one-day seminars each year on practice marketing and practice management, and workshops for physicians' office staff.

Membership

Recruitment is generally the first way Faculty staff assists its membership: staff contact with a Maryland physician may occur before the physician receives his/her license (through membership in the Student Society) or before the physician becomes a resident of Maryland. Each week the American Medical Association (AMA) distributes a newsletter reporting lists of newly licensed physicians and physicians moving to Maryland. Public Relations/Membership Coordinator Nina Casey, using these lists, follows up with letters of invitation and information about joining Med-Chi. From time to time Casey targets specific groups (such as nonmember physicians in Maryland medical universities) for membership drives.

Membership applications are processed by Membership Secretary Doris Cicchini, who collects membership dues, keeps records, and corresponds with component societies about membership. Cicchini always has the latest figures on Faculty membership. Changes of address and phone numbers should be directed to her office.



McGibbon



Schram



Cicchini

Finance



Buckmaster



Parker

The financial department at Med-Chi requires the services of two full-time Accounting Clerks, Karen Buckmaster and Michelle Parker. Buckmaster oversees several accounts including Center for Health Education, Med-Chi Agency (insurance), and MMPAC. She keeps the general ledger for Med-Chi up-to-date on Med-Chi's computer. Parker does bookkeeping and filing for the financial department of Med-Chi. She keeps track of invoices and cash receipts, types and posts outgoing checks, and bills physicians for dinner meetings.

Assistant Comptroller Philip Moore accomplishes a wide variety of tasks. In addition to keeping financial records and dues records and generating financial reports, he coordinates all Med-Chi's financial data computer files. He provides the staff with mailing labels from the computer, printouts of statistical data (for example, distribution of members in a certain specialty by county), and educated guesses and treatment when the computer system is uncooperative.

Novella Wallace-Frantz is Executive Secretary to the Associate Executive Director and Comptroller, Joseph Harrison. She maintains personnel records, keeps inventory records and purchases supplies, processes billing for *MMJ* advertising, and does accounting for Annual and Semiannual Meetings.

Associate Executive Director and Comptroller Joseph Harrison oversees the financial and business workings of the Faculty. In cooperation with the Budget Committee, he writes and implements the Med-Chi Budget and monitors appropriation of funds. Harrison is personnel and benefits director and a welcome sight on staff paydays: he hand delivers each staff members' check.

Harrison serves as Secretary for the Board of Directors of the Med-Chi Insurance Fund and Secretary-Treasurer of the Med-Chi Agency, which provides insurance, as well as financial and loan planning services for Faculty membership. He is Treasurer for Maryland



Moore



Wallace-Frantz



Harrison

Medical Political Action Committee. In addition to these responsibilities, he attends meetings of the Council, Executive Committee, House of Delegates, Bylaws Committee, Reference Committee, Finance Committee, and other Med-Chi committees upon request.

Library

Few other state medical societies offer library services to their members. The Med-Chi Library comprises the History of Medicine and Rare Book Collection, Technical Services, and Public Services, and is uniquely qualified to provide information, and the staff responds to a request the same day it is received. Members are entitled to five photocopied articles each month free of charge. Since the Faculty underwrites costs of literature searches, this service is available to the physician member at a much lower rate than through a university library. Computers allow staff to complete literature searches, send information to physicians, communicate with component societies, and store information, thus expanding the information sources available to members.

The Library now has over 120,000 volumes and journals, including 18,000 volumes in the History of Medicine and Rare Book Collection. When School #49 is completed, the Library staff will work in the present Faculty building's expanded Library facilities.

Anticipating and serving the clinical information needs of the Faculty's members demands the efforts of several Med-Chi staff. Joseph Jensen, Library Director, is overall administrator of the Library staff. He manages the Library budget, which is supported by Faculty dues and endowed funds. Jensen spends several days each month consulting with libraries at Maryland hospitals on behalf of Med-Chi. The Computers in Medicine Committee, Library Committee, and Finney Fund Committee are staffed by Jensen. He coordinates the Library Page, a monthly feature of *MMJ*, and has written many articles on the history of Maryland's medical society, its Library, and its future. The renovation of School #49 and the corresponding update of Library facilities within the 1211 Cathedral Street building have kept Jensen actively involved in ensuring plans and designs fit the long-term needs of the Library.

The History of Medicine and Rare Book Collection of the Faculty Library is headed by Deborah Woolverton. Woolverton carefully oversees the conservation of the division's 18,000 books. She has created several exhibits for the halls of Med-Chi and Faculty Annual Meetings using photographs, medical equipment, and information from the History of Medicine collection. Woolverton processes donations from physicians and organizes the Rare Book Collection as well as Med-Chi archives. Duplicate copies are sold through the Chirurgical Bookshop. She is available by appointment to answer historical reference questions.

Woolverton receives assistance from Lisa Mix. Mix is involved in organizing the Med-Chi archives: sifting through old records, Annual Meeting programs, and transactions of the Faculty. She collaborated on the exhibit for the 1985 Annual Meeting and adapted the information for publication in *MMJ*'s Library Page.



Jensen



Woolverton



Mix



Munoz



Karin

Pat Munoz, Cataloging and Acquisitions Specialist, directs the Technical Services division of the Faculty Library. She supervises journal and book ordering and journal binding for the Library. Munoz planned and manages a book and journal ordering service for 23 hospitals in the District of Columbia, Maryland, and Virginia area. Physicians may order books through Munoz's office.

Charlotte Karin, Cataloging and Acquisitions Assistant, works with Munoz in Technical Services. Karin processes orders for books and, upon receipt, provides cataloging information for the Med-Chi Library and the hospitals served by the Med-Chi Library. Karen Mosca, Serials Assistant, receives journals in the Library Technical Services office, shelves those ordered by the Faculty Library, and distributes those ordered through the Faculty Library by area hospitals. She assists in binding journals at the end of each year.

Adam Szczepaniak, Associate Librarian, heads the Public Services division of the Library. Szczepaniak manages the day-to-day administrative work of the division. He answers reference calls, performs literature searches, instructs Library staff in the use of new computer software and databases, and frequently contributes to *MMJ*'s Library Page. His latest articles alert physicians to computer services and education available through the Med-Chi Library.

Literature searches keep Reference and Circulation Librarian Susan Harmon constantly at the computer. She performs literature searches primarily for members; Faculty staff require searches on legislative issues, and Harmon often receives requests from Baltimore law firms. In *MMJ* she lists selected medical literature searches from among those she completes each month. In addition Harmon follows library professional news, keeps track of book circulation, and prepares bibliographies for scientific programs at Med-Chi's Annual Meeting.



Mosca



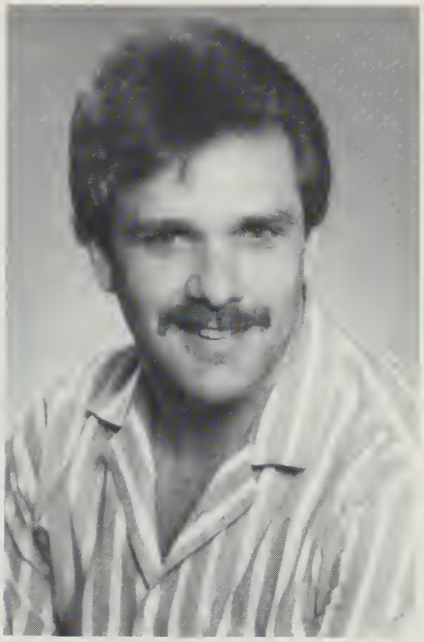
Szczepaniak



Harmon



Griebel



Buscher



Beil

Wanda Griebel, Reference and Circulation Assistant, processes orders for photocopying and interlibrary loans and prepares billing for these services. She assists Szczepaniak and Harmon in answering reference calls and providing assistance to physicians visiting the Library.

Maintenance

Mike Buscher and John Beil accomplish a wide variety of tasks for the Faculty. Buscher carries out maintenance and repair jobs for the Faculty building and was instrumental in the recent renovation of the Faculty's kitchen. He delivers Faculty mail to the post office and keeps the Med-Chi's postage meter supplied. Buscher often closes the Faculty building at the end of the day. Beil, who also worked on the kitchen renovation, assists Buscher with the maintenance work load. Beil and Buscher provide photocopying services for the Library.

Custodian Laura Mae Frazier manages the Faculty kitchen. She cooks lunches daily for John Sargeant and Joseph Harrison, keeps the teakettle warm, and prepares dinners for the many committee meetings held in Osler Hall. Frazier arranges Osler Hall to meet the requirements of different committee programs and, as the last to leave after a night's meetings, closes the Faculty Building. Custodian Leatha Hardy provides housekeeping services for the Faculty building. She opens the building each morning, answers phone calls until the switchboard opens at 9 a.m., admits staff and visitors, and always has a fresh pot of coffee ready to greet the staff each morning.



Frazier



Hardy



Wilt

Receptionist and PBX Operator June Wilt channels all calls to the Faculty offices. She is helpful in directing callers' queries to the appropriate staff and will take messages if staff are unavailable. Wilt helps other staff members with mailings and posts the daily meeting schedule on the hall bulletin board.

Faculty Expansion

Med-Chi continues to expand its responsibilities to meet the needs of its membership. Since June 1, all physicians with hospital privileges have been required to have a common identification number for use at hospitals where their privileges are maintained. Hospitals are submitting lists of privileged physicians to the Faculty for identification number assignment. Maintaining CME Category I credit records for physicians is another major new service the Faculty offers. Both programs require staff support.

Library and record storage requirements have increased dramatically since 1909. The Faculty building housed only five staff members that year: today nearly forty Med-Chi staff look forward to the new offices and Library development made possible by renovation of School #49.

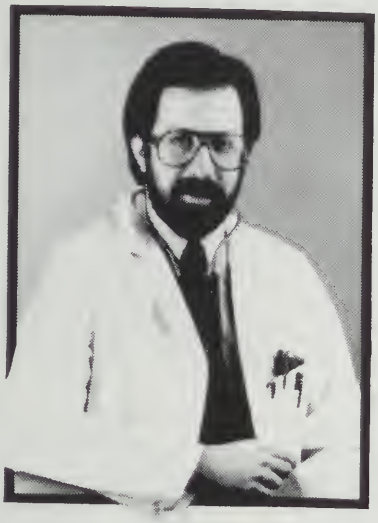
The future of quality health care is assured by physician involvement and action in changes in practice management, medical economics, and advances in medical care. This evolution demands that today's physician be well-informed. Call on the Faculty staff to provide you with the information and support you need.

Staff photos by TADDER/Baltimore.

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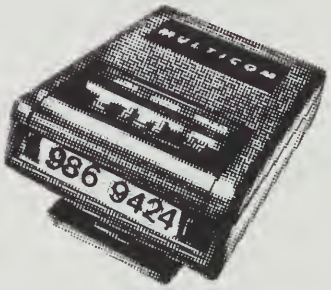
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Information for Authors

Med-Chi members reading papers before organizations are invited to submit their papers to the MMJ for consideration for publication.

The *Maryland Medical Journal* is the monthly publication of the Medical and Chirurgical Faculty of the State of Maryland. Its goals are educational and informative: the publishing of scientific articles and other technical information as well as editorials, special articles (evaluations, position papers, reviews of nonscientific subjects), membership news, notices of medical events, legislative and governmental news, meetings, continuing education courses, and programs and policies of the Faculty.

Manuscripts may be sent to Editor *MMJ*, 1211 Cathedral St., Baltimore, MD 21201. Articles are accepted for publication on the condition that they are contributed solely to this journal. Transmittal letters should designate one author as correspondent and include his/her address and telephone number. Manuscripts are reviewed by the editor, editorial board members, and guest reviewers. The final decision is reserved for the Editor.

Specifications

Manuscripts must be original typed copy, double-spaced throughout (including text, case reports, legends, tables, and references) with margins of at least one inch. Number pages consecutively. Please submit two additional copies.

Include in the manuscript the concise title, full name of the author (or authors) with highest degree, academic and professional titles, affiliations, and any institutional or other credits.

An introductory synopsis/abstract of approximately 100–150 words is required.

Tables are to be typed on separate sheets of paper, numbered, and have a brief descriptive title. The Editor reserves the right to edit tables. Be sure that statistics are consistent in both tables and text.

References are limited to those citations noted in the text. References are to be typed double-spaced and numbered consecutively as they appear in text. They will be examined critically at the time of review and must be kept to a minimum. Personal communications and unpublished data should not be included. The following are necessary: names of all authors, complete title of article cited (lower case), name of journal abbreviated according to *Index Medicus*, volume number, first and last page numbers, and year of publication. For more extensive information about preparing medical articles for publication, the editors suggest the International Committee of Medical Journal Editors: Uniform requirements for manuscripts submitted to biomedical journals. The complete document is available in the June 1982 issue of the *Annals of Internal Medicine*.

Illustrations are material that cannot be set in type. Photographic material must be submitted as high-contrast, glossy prints. Drawings and graphs must be done professionally in india ink on high-grade white drawing paper. *Omit illustrations that do not increase understanding of text, and limit them to a reasonable number.* Four or fewer illustrations should be adequate for a manuscript of 4 to 5 typed pages. Legends are to be typed on a separate sheet of paper. Type on a gummed label and affix to the back of each illustration: figure number, title of manuscript, name of senior author, and arrow indicating top. Legends for illustrations should be typed on a separate page with numbers corresponding to those on the photographs and drawings. *Cost of printing color photographs must be borne by the author.*

Recognizable photos of patients are to be masked and should carry with them written permission for publication.

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Editorial Responsibility

Manuscripts are subject to editorial modification and such revisions necessary to being them into conformity with *Journal* style.

Galley proofs will be mailed to the principal author and, if not returned by the specified date, will be considered approved as typeset.

Statements made or opinions expressed by any contributor in any article or feature published in the *Journal* are the sole responsibility of the author.



AFTER BREAKTHROUGH BLEEDING AND AMENORRHEA...
SHE'S ABOUT TO GIVE UP ON ORAL CONTRACEPTION.

NORLESTRIN®

(1 mg norethindrone acetate and 50 mcg ethinyl estradiol tablets, USP) 1/50

BECAUSE SOMETIMES A 50 IS PREFERABLE.

See next page for brief summary of prescribing information.

Brief Summary of Prescribing Information
NORLESTRIN® (norethindrone acetate and ethinyl estradiol tablets, USP)

See section under **Special Notes on Administration and HOW SUPPLIED.**
Before prescribing, please see full prescribing information. A Brief Summary follows.

DESCRIPTION
Norlestrin Products are progestogen-estrogen combinations.

INDICATIONS AND USAGE
Norlestrin Products are indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

In clinical trials with Norlestrin 1/50 involving 25,983 therapy cycles, there was a pregnancy rate of 0.05 per 100 woman-years; in clinical trials with Norlestrin 2.5/50 involving 96,388 cycles, there was a pregnancy rate of 0.22 per 100 woman-years.

Dose-Related Risk of Thromboembolism from Oral Contraceptives: Studies have shown a positive association between the dose of estrogens in oral contraceptives and the risk of thromboembolism. It is prudent and in keeping with good principles of therapeutics to minimize exposure to estrogen. The oral contraceptive prescribed for any given patient should be that product which contains the least amount of estrogen that is compatible with an acceptable pregnancy rate and patient acceptance.

CONTRAINDICATIONS
1. Thrombophlebitis or thromboembolic disorders
2. A past history of deep-vein thrombophlebitis or thromboembolic disorders
3. Cerebral vascular or coronary artery disease
4. Known or suspected carcinoma of the breast
5. Known or suspected estrogen-dependent neoplasia
6. Undiagnosed abnormal genital bleeding
7. Known or suspected pregnancy (See WARNING No. 5)
8. Benign or malignant liver tumor which developed during the use of oral contraceptives or other estrogen-containing products.

WARNINGS

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

The use of oral contraceptives is associated with increased risk of several serious conditions including thromboembolism, stroke, myocardial infarction, hepatic adenoma, gallbladder disease, and hypertension. Practitioners prescribing oral contraceptives should be familiar with the following information relating to these risks.

1. *Thromboembolic Disorders and Other Vascular Problems.* An increased risk of thromboembolic and thrombotic disease associated with the use of oral contraceptives is well-established. Studies have demonstrated an increased risk of fatal and nonfatal venous thromboembolism and stroke, both hemorrhagic and thrombotic.

Cerebrovascular Disorders: In a collaborative study in women with and without predisposing causes, it was estimated that the risk of hemorrhagic stroke was 2.0 times greater in users than nonusers, and the risk of thrombotic stroke was 4.0 to 9.5 times greater.

Myocardial Infarction: An increased risk of myocardial infarction associated with oral contraceptives has been reported confirming a previously suspected association. These studies found that the greater the number of underlying risk factors (cigarette smoking, hypertension, hypercholesterolemia, obesity, diabetes, history of preeclamptic toxemia) for coronary artery disease, the higher the risk of developing myocardial infarction, regardless of whether the patient was an oral contraceptive user or not. Oral contraceptives, however, were found to be a clear additional risk factor.

It has been estimated that users who do not smoke (smoking is considered a major predisposing condition to myocardial infarction) are about twice as likely to have a fatal myocardial infarction as nonusers who do not smoke. Oral contraceptive users who are smokers have about a fivefold increased risk of fatal infarction compared to users who do not smoke, but about a tenfold to twelvefold increased risk compared to nonusers who do not smoke. The amount of smoking is also an important factor.

Risk of Dose: In an analysis of data, British investigators concluded that the risk of thromboembolism, including coronary thrombosis, is directly related to the dose of estrogen used in oral contraceptives; however, the quantity of estrogen may not be the sole factor involved.

Persistence of Risk: Two studies have suggested that an increased risk may persist for as long as 6 years after discontinuation of oral contraceptive use for cerebrovascular disease and 9 years for myocardial infarction. In addition, a prospective study suggested the persistence of risk for subarachnoid hemorrhage.

Estimate of Excess Mortality from Circulatory Diseases: The risk of diseases of the circulatory system is concentrated in older women, in those with a long duration of use, and in cigarette smokers.

A study of available data from a variety of sources concluded that the mortality associated with all methods of birth control is low and below that associated with childbirth, with the exception of oral contraceptives in women over 40 who smoke.

The risk of thromboembolic and thrombotic diseases associated with oral contraceptives increases with age after approximately age 30 and, for myocardial infarction, is further increased by hypertension, hypercholesterolemia, obesity, diabetes, or history of preeclamptic toxemia, and especially by cigarette smoking.

The physician and the patient should be alert to the earliest manifestations of thromboembolic and thrombotic disorders. Should any occur or be suspected, the drug should be discontinued immediately.

A fourfold to sixfold increased risk of postsurgery thromboembolic complications has been reported in users. If feasible, oral contraceptives should be discontinued at least four weeks before surgery of a type associated with an increased risk of thromboembolism or prolonged immobilization.

2. *Ocular Lesions.* Neuro-ocular lesions, such as optic neuritis or retinal thrombosis, have been associated with the use of oral contraceptives. Discontinue the oral contraceptive if there is unexplained sudden or gradual, partial, or complete loss of vision; onset of proptosis or diplopia; papilledema; or retinal vascular lesions.

3. *Carcinoma.* Long-term continuous administration of estrogen in certain animal species increases the frequency of carcinoma of the breast, cervix, vagina, and liver.

In humans, an increased risk of endometrial carcinoma associated with the prolonged use of exogenous estrogen in postmenopausal women has been reported. However, there is no evidence suggesting increased risk of endometrial cancer in users of conventional combination or progestogen-only oral contraceptives.

Studies found no evidence of increase in breast cancer in women taking oral contraceptives; however, an excess risk in users with documented benign breast disease was reported.

There is no confirmed evidence of an increased risk of cancer associated with oral contraceptives. Close clinical surveillance of users is, nevertheless, essential. In cases of undiagnosed persistent or recurrent abnormal vaginal bleeding, appropriate diagnostic measures should be taken to rule out malignancy. Women with a strong family history of breast cancer, or who have breast nodules, fibrocystic disease, or abnormal mammograms, should be monitored with particular care.

4. *Hepatic Tumors.* Benign hepatic adenomas have been found to be associated with oral contraceptives. Because hepatic adenomas may rupture and may cause death through intra-abdominal hemorrhage, they should be considered in women presenting abdominal pain and tenderness, abdominal mass, or shock.

A few cases of hepatocellular carcinoma have been reported in women taking oral contraceptives. The relationship of these drugs to this type of malignancy is not known at this time.

5. *Usage in or Immediately Preceding Pregnancy; Birth Defects in Offspring, and Malignancy in Female Offspring.* During early pregnancy, female sex hormones may seriously damage the offspring.

An increased risk of congenital anomalies, including heart defects and limb defects, has been reported with the use of oral contraceptives in pregnancy.

There is some evidence that triploidy and possible other types of polyploidy are increased among abortuses from women who become pregnant soon after ceasing oral contraceptives.

Pregnancy should be ruled out before continuing an oral contraceptive in any patient who has missed two consecutive menstrual periods. If the patient has not adhered to the schedule, the possibility of pregnancy should be considered at the time of the first missed period, and oral contraceptives should be withheld until pregnancy has been ruled out. If pregnancy is confirmed, the patient should be apprised of the potential risks to the fetus and the advisability of continuation of the pregnancy should be discussed.

Women who discontinue oral contraceptives with the intent of becoming pregnant should use an alternate form of contraception for a period of time before attempting to conceive.

Administration of progestogen-only or progestogen-estrogen combinations to induce withdrawal bleeding should not be used as a test of pregnancy.

6. *Gallbladder Disease.* Studies report an increased risk of surgically confirmed gallbladder disease in users of oral contraceptives.

7. *Carbohydrate and Lipid Metabolic Effects.* Because decreased glucose tolerance has been observed in a significant percentage of patients, prediabetic and diabetic patients should be carefully observed while receiving oral contraceptives.

An increase in triglycerides and total phospholipids has been observed.

8. *Elevated Blood Pressure.* An increase in blood pressure has been reported in patients receiving oral contraceptives. The prevalence in users increases with longer exposure. Age is also strongly correlated with development of hypertension. Women who previously have had hypertension during pregnancy may be more likely to develop elevation of blood pressure.

9. *Headache.* Onset or exacerbation of migraine or development of headache of a new pattern which is recurrent, persistent, or severe, requires discontinuation of oral contraceptives.

10. *Bleeding Irregularities.* Breakthrough bleeding, spotting, and amenorrhea are frequent reasons for patients discontinuing oral contraceptives. In breakthrough bleeding, nonfunctional causes should be borne in mind. In undiagnosed abnormal bleeding from the vagina, adequate diagnostic measures are indicated to rule out pregnancy or malignancy.

Women with a past history of oligomenorrhea or secondary amenorrhea, or young women without regular cycles should be advised that they may have a tendency to remain anovulatory or to become amenorrheic after discontinuation of oral contraceptives.

11. *Ectopic Pregnancy.* Ectopic as well as intrauterine pregnancy may occur in contraceptive failures.

12. *Breast-Feeding.* Oral contraceptives may interfere with lactation. Furthermore, a small fraction of the hormonal agents in oral contraceptives has been identified in the milk of mothers receiving these drugs.

PRECAUTIONS
1. A complete medical and family history should be taken prior to the initiation of oral contraceptives. The pretreatment and periodic physical examinations should include special reference to blood pressure, breasts, abdomen, and pelvic organs, including Papanicolaou smear and relevant laboratory tests. As a general rule, oral contraceptives should not be prescribed for longer than one year without another examination.
2. Preexisting uterine leiomyomata may increase in size.
3. Patients with a history of psychic depression should be carefully observed and the drug discontinued if depression recurs to a serious degree.
4. Oral contraceptives may cause fluid retention and should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated.
5. Patients with a past history of jaundice during pregnancy have an increased risk of recurrence of jaundice. If jaundice develops, the medication should be discontinued.
6. Steroid hormones may be poorly metabolized and should be administered with caution in patients with impaired liver function.
7. Users may have disturbances in normal tryptophan metabolism, which may result in a relative pyridoxine deficiency.
8. Serum folate levels may be depressed.
9. The pathologist should be advised of oral contraceptive therapy when relevant specimens are submitted.
10. Certain endocrine and liver function tests and blood components may be affected. (a) Increased sulfobromophthalein retention. (b) Increased prothrombin and factors VII, VIII, IX, and X; decreased antithrombin 3, increased norepinephrine-induced platelet aggregability. (c) Increased thyroid-binding globulin (TBG) leading to increased circulating total thyroid hormone. (d) Decreased pregnanediol excretion. (e) Reduced response to metyrapone test.

Drug Interactions: Reduced efficacy and increased incidence of breakthrough bleeding have been associated with concomitant use of rifampin. A similar association has been suggested with barbiturates, phenylbutazone, phenytoin sodium, tetracycline, and ampicillin.

ADVERSE REACTIONS
An increased risk of the following serious adverse reactions has been associated with oral contraceptives: thrombophlebitis; pulmonary embolism; coronary thrombosis, cerebral thrombosis; cerebral hemorrhage; hypertension; gallbladder disease; benign hepatomas, congenital anomalies.

There is evidence of an association between the following conditions and the use of oral contraceptives, although additional confirmatory studies are needed: mesenteric thrombosis, neuro-ocular lesions, eg, retinal thrombosis and optic neuritis.

The following adverse reactions have been reported in patients receiving oral contraceptives and are believed to be drug related: nausea and/or vomiting, usually the most common adverse reactions, occur in approximately 10% or less of patients during the first cycle. Other reactions, as a general rule, are seen much less frequently or only occasionally: gastrointestinal symptoms; breakthrough bleeding; spotting; change in menstrual flow; dysmenorrhea; amenorrhea during and after treatment; temporary infertility after discontinuance of treatment; edema; chloasma or melasma; breast changes; change in weight; change in cervical erosion and cervical secretion; possible diminution in lactation when given immediately postpartum; cholestatic jaundice; migraine; increase in size of uterine leiomyomata; rash (allergic); mental depression; reduced tolerance to carbohydrates; vaginal candidiasis; change in corneal curvature; intolerance to contact lenses.

The following adverse reactions have been reported and the association has been neither confirmed nor refuted: premenstrual-like syndrome; cataracts; changes in libido; chorea; changes in appetite; cystitis-like syndrome; headache; nervousness; dizziness; hirsutism; loss of scalp hair; erythema multiforme; erythema nodosum; hemorrhagic eruption; vaginitis; porphyria.

Special Notes on Administration
Menstruation usually begins two or three days, but may begin as late as the fourth or fifth day, after discontinuing medication.

After several months on treatment, bleeding may be reduced to a point of virtual absence; reduced flow may be a result of medication and not indicative of pregnancy.

HOW SUPPLIED
Norlestrin 21 1/50 is available in compacts each containing 21 tablets. Each tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

Norlestrin 21 2.5/50 is available in compacts each containing 21 tablets. Each tablet contains 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

Norlestrin Fe 1/50 is available in compacts each containing 21 yellow tablets and 7 brown tablets. Each yellow tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Each brown tablet contains 75 mg of ferrous fumarate, USP. Available in packages of five compacts and packages of five refills.

Norlestrin FE 2.5/50 is available in compacts each containing 21 pink tablets and 7 brown tablets. Each pink tablet contains 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Each brown tablet contains 75 mg of ferrous fumarate, USP. Available in packages of five compacts and packages of five refills.

Norlestrin 28 1/50 is available in compacts each containing 21 yellow tablets and 7 white inert tablets. Each yellow tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

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PD-21-JA-2563-P-1(11-84)

Discipline Commission Action

In the Matter of
George H. Beck MD
Before the Commission
on Medical Discipline

Order Terminating Probation and Reinstating License

By order dated May 14, 1970 (the "1970 Order") the Commission on Medical Discipline (the "Commission") found George H. Beck MD (the "Respondent") guilty of addiction to narcotics, pursuant to Maryland Annotated Code, Section 14-504(9) of the Health Occupations Article, and revoked the medical license of Respondent subject to certain indefinite conditions (the "Conditions of Probation"). The Order further provided that if Respondent complied satisfactorily with the Conditions of Probation, the Commission would entertain a petition for termination of Respondent's probationary status and reinstatement of his medical license without any conditions or restrictions. On February 8, 1984, Respondent petitioned the Commission for reinstatement of his license to practice medicine in Maryland without any conditions or restrictions. At its meeting on March 6, 1984, the Commission reviewed Respondent's petition for reinstatement. Based upon its review of the petition, the Commission determined that Respondent had fulfilled the Conditions of Probation contained in the 1970 Order.

Findings of Fact

The Commission finds that Respondent has satisfactorily complied with all the Conditions of Probation imposed by the Commission's 1970 Order.

Conclusions of Law

The Commission concludes, as a matter of law, that it is appropriate to terminate Respondent's Conditions of Probation and to reinstate his license without any condition or restriction.

Order

Upon the foregoing Findings of Fact and Conclusions of Law, it is this 6th day of March 1984, by a unanimous vote of a quorum of the Commission:

ORDERED that effective as of the date of this Order, the Conditions of Probation imposed upon Respondent's practice of medicine by the Commission's 1970 Order are hereby TERMINATED and of no further force and effect; and be it further

ORDERED that Respondent's license to practice medicine in the State of Maryland be REINSTATED without any condition or restriction whatsoever.

HILARY T. O'HERLIHY **MD, Chairman**
Commission on Medical Discipline of Maryland

On instruction of the Council of the Medical and Chirurgical Faculty of the State of Maryland, "Findings of Fact, Conclusions of Law, and Order" will be published in the Maryland Medical Journal.

In the Matter of
Robert C. Brown MD
78 Kakley Street
Albany, New York 12208
Before the Commission
on Medical Discipline

Findings of Fact
Conclusion of Law and Order

Based upon information coming to its attention, the Commission on Medical Discipline of Maryland (the "Commission") after investigation determined to charge Robert C. Brown MD ("Respondent") with violations of the Maryland Medical Practice Act, Health Occupations Article, Maryland Code Annotated, §14-101 *et seq.* Specifically, Respondent was charged with a violation of §14-504(22) of the Act as follows:

(1) Is disciplined by a licensing or disciplinary authority for an act that would be grounds for disciplinary action under this Section.
(2) Fraudulently or deceptively uses a license:
(3) Is guilty of immoral conduct in the practice of medicine;
(4) Is professionally incompetent; and
(6) Is convicted of and pleads guilty with respect to a crime involving moral turpitude.

Respondent was notified of the charges by letter dated May 3, 1984.

Findings of Fact

Based upon the information in its files, and otherwise made known to it, the Commission finds:

1. The Respondent at all times relevant to the proceedings was an individual licensed to practice medicine in Maryland is currently licensed to practice medicine in Maryland.

2. On October 31, 1983, Respondent's license to practice medicine in the State of New York was suspended as a result of Respondent's entering into a Consent Agreement ("Consent Agreement") with the Department of Health, State Board of Professional Medical Conduct. ("the Board") (attached hereto);

3. The suspension of license by the Board was stayed after six (6) months and Respondent was placed on probation for two and one half (2½) years subject to certain terms and conditions of probation as set forth in the Consent Agreement;

4. The suspension of Respondent's license by the Board related to conduct which formed a basis for disciplinary action under §14-504(2), (3), (4) and (6) of the Act; specifically Respondent admitted prescribing controlled dangerous substances without medical justification or necessity and was convicted of same;

6. On March 6, 1984, Respondent's license was returned by the New York State Licensing Board.

Conclusion of Law

Based upon the foregoing Findings of Fact, the Maryland Commission on Medical Discipline, by a unanimous vote of those members considering the above case, concludes as a matter of law that Respondent violated Section 14-504(22) of the Maryland Medical Practice Act.

Order

Based upon the foregoing Findings of Fact and Conclusion of Law, it is this 30th day of April 1985, by unanimous vote of those members of the Maryland Commission on Medical Discipline considering the above case,

ORDERED that the Maryland license to practice medicine of Respondent, Robert C. Brown MD, be hereby SUSPENDED, and be it further

ORDERED that the SUSPENSION of said license be and is hereby immediately STAYED and Respondent placed on PROBATION subject to the following terms and conditions:

1. Respondent shall comply with the conditions of probations set forth in paragraphs 1–3 of the New York Consent Agreement, specifically
   a. That Respondent shall conduct himself in all ways in a manner befitting his professional status, and shall conform fully to the moral and professional standards of conduct imposed by law and by his profession:
   b. That Respondent shall submit written notification to the New York State Education Department, addressed to the Executive Director, Office of Professional Discipline, 622 Third Avenue, New York, N.Y. 10017, of any employment and practice, of his residence and telephone number, of any change in his employment, practice, residence, or telephone number within or without the State of New York:
   c. That Respondent shall submit proof to the New York State Education Department, addressed to the Executive Director, Office of Professional Discipline, as aforesaid, that Respondent is currently registered with the New York State Education Department and has paid any fines that may have previously been imposed upon Respondent by the Board of Regents, said proof to be submitted no later than the first two months of the period of probation.
2. If Respondent returns to Maryland to practice medicine, he shall immediately notify the Commission on Medical Discipline identifying his employer, describing his job duties and responsibilities;
3. Respondent shall refrain from any and all activity in any way similar or related to the conduct that resulted in the disciplinary action against him in the State of New York; and
4. Respondent shall practice in accordance of the Medical Practice Act; and be it further

ORDERED if Respondent violates any of the foregoing conditions of probation, the Commission, after notification and a hearing, may lift the stay and impose any disciplinary sanction it deems appropriate; and be it further

ORDERED that upon successful completion of Respondent's conditions of probations in New York and full restoration of his certificate to practice medicine in the State of New York without restrictions, the Commission will entertain a petition for termination of Respondent's probationary status. At such time, if the Commission determines that the termination of probation is not appropriate, the Commission may alternatively modify one or more of the conditions upon which the Respondent was placed on probation. However, in order to have the petition for termination of probation considered, the Respondent must demonstrate to the Commission that he has met all the continuing educational requirements necessary in Maryland in order to have a license renewed.

HILARY T. O'HERLIHY MD, **Chairman**
Commission on Medical Discipline of Maryland

Consent

By this Consent, knowingly and voluntarily executed by me, I hereby consent and submit to the foregoing Order and its conditions. I acknowledge the validity of the Order as if made after a hearing at which time I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my behalf and to all other substantive and procedural protections provided by law. I also recognize that I am waiving my rights to appeal any adverse ruling of the Maryland State Commission on Medical Discipline that might have followed any such hearing. By this Consent, I waive all such rights.

ROBERT C. BROWN **MD**

• • •

In the Matter of Richard Forde MD Before the Commission On Medical Discipline

Notification of Termination of Probation and Reinstatement of Medical License

By Order dated November 26, 1980 (the "1980 Order"), the Commission on Medical Discipline (the Commission) found Richard Forde MD (the "Respondent") guilty of violating Article 43, §130(h)(4) of the Annotated Code (recodified at §14-504(6) of the Health Occupations Article). The Commission revoked the medical license of the Respondent, but stipulated that as of May 26, 1981, the revocation be stayed and that Respondent be placed on probation subject to certain conditions (the "Conditions of Probation"). The Order

further provided that if, after two and a half years from the date of the stay of the revocation, Dr. Forde complied satisfactorily with the Conditions of Probation, his license to practice medicine in the State of Maryland would be reinstated.

On November 26, 1983,* the medical license of Richard Forde MD was automatically reinstated in the State of Maryland without any conditions or restrictions whatsoever.

HILARY T. O'HERLIHY **MD, Chairman**
Commission on Medical Discipline of Maryland

• • •

In the Matter of Andres C. Gomez MD Before the Commission on Medical Discipline

Order Terminating Probation and Reinstating License

By order dated August 15, 1980 (the "1980 Order") the Commission on Medical Discipline (the "Commission") found Andres C. Gomez MD (the "Respondent") guilty of professional incompetence, pursuant to Maryland Annotated Code, Article 43, 130(h)(18) recodified at Subsection 14-504(4) of the Health Occupations Article, and revoked the medical license of Respondent subject to certain conditions (the "Conditions of Probation"). The Order further provided that if Respondent complied satisfactorily with the Conditions of Probation the Commission would entertain a petition for termination of Respondent's probationary status and reinstatement of his medical license without any conditions or restrictions. On June 15, 1984, Respondent petitioned the Commission for reinstatement of his license to practice medicine in Maryland without any conditions or restrictions. At its meeting of July 17, 1984, the Commission reviewed Respondent's petition for reinstatement. Based upon its review of the petition, the Commission determined that Respondent had fulfilled the Conditions of Probation contained in the August 15, 1980 Order.

Findings of Fact

The Commission finds that Respondent has satisfactorily complied with all the Conditions of Probation imposed by the Commission's 1980 Order.

Conclusions of Law

The Commission concludes, as a matter of law, that it is appropriate to terminate Respondent's Conditions of Probation and to reinstate his license without any condition or restriction.

Order

Upon the foregoing Findings of Fact and Conclusions of Law, it is this 17th day of July 1984,† by a unanimous vote of a quorum of the Commission:

ORDERED that effective as of the date of this Order, the Conditions of Probation imposed upon Respondent's practice of medicine by the Commission's 1980 Order are hereby TERMINATED and of no further force and effect; and be it further

ORDERED that Respondent's license to practice medicine in the State of Maryland be REINSTATED without any condition or restriction whatsoever.

HILARY T. O'HERLIHY **MD, Chairman**
Commission on Medical Discipline of Maryland

In the Matter of Martin Meltzer MD Before the Commission on Medical Discipline

Order Terminating Probation and Reinstating License

By Order dated November 3, 1981 (the "1981 Order") the Commission on Medical Discipline (the "Commission") found Martin Meltzer MD (the "Respondent") guilty of being disciplined by a licensing authority of another state, pursuant to Maryland Annotated Code, Section 14-504(22) of the Health Occupations Article, and revoked the medical license of Respondent subject to certain conditions (the "Conditions of Probation"). The Order further provided that after three (3) years from the date of the Order, if Respondent complied satisfactorily with the Conditions of Probation, the Commission would entertain a petition for termination of Respondent's probationary status and reinstatement of his medical license without any conditions or restrictions. On April 18, 1985, Respondent petitioned the Commission for reinstatement of his license to practice medicine in Maryland without any conditions or restrictions. At its meeting on April 30, 1985, the Commission reviewed Respondent's petition for reinstatement. Based upon its review of the petition, the Commission determined that Respondent had fulfilled the Conditions of Probation contained in the 1981 Order.

Findings of Fact

The Commission finds that Respondent has satisfactorily complied with all the Conditions of Probation imposed by the Commission's 1981 Order.

* Received in *MMJ* office 6/4/85.

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Conclusions of Law

The Commission concludes, as a matter of law, that it is appropriate to terminate Respondent's Conditions of Probation and to reinstate his license without any condition or restriction.

Order

Upon the foregoing Findings of Fact and Conclusions of Law, it is this 21st day of May, 1985, by a unanimous vote of a quorum of the Commission:

ORDERED that effective as of the date of this Order, the Conditions of Probation imposed upon Respondent's practice of medicine by the Commission's 1981 Order are hereby TERMINATED and of no further force and effect; and be it further

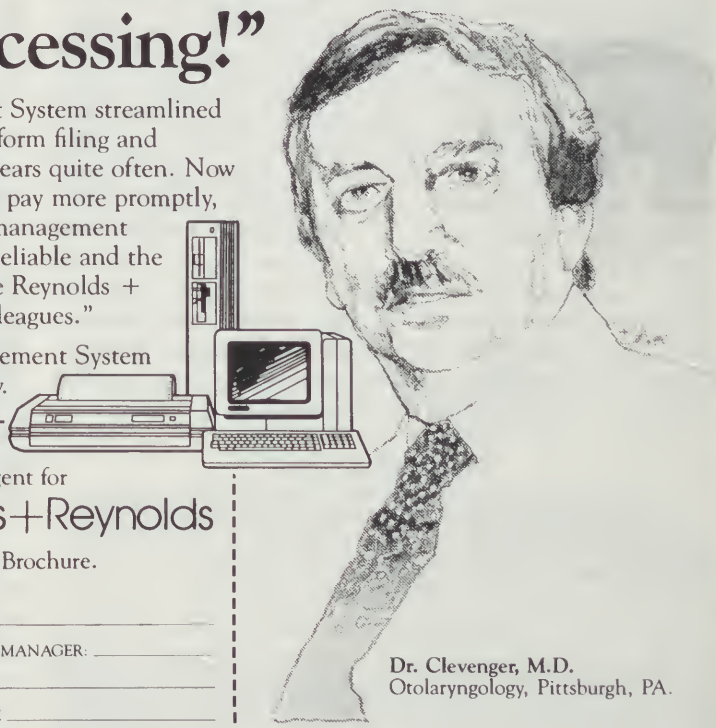
ORDERED that Respondent's license to practice medicine in the State of Maryland be REINSTATED without any condition or restriction whatsoever.

HILARY T. O'HERLIHY **MD, Chairman**
Commission on Medical Discipline of Maryland

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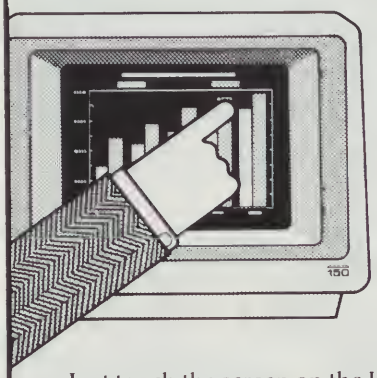
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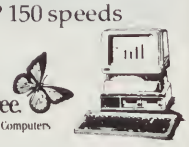
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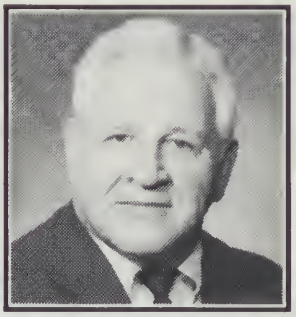
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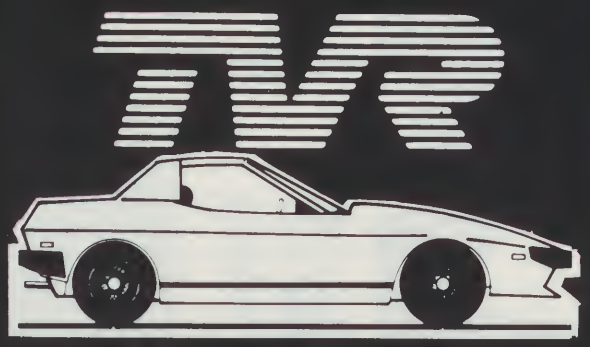
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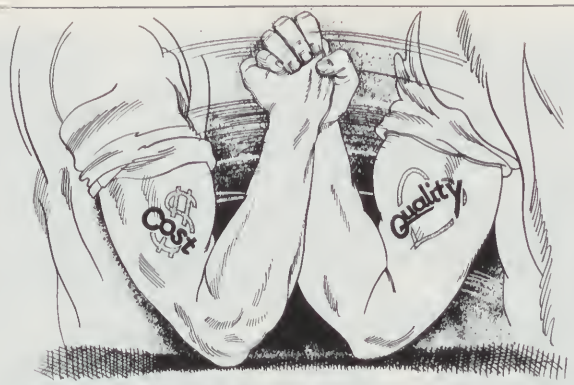
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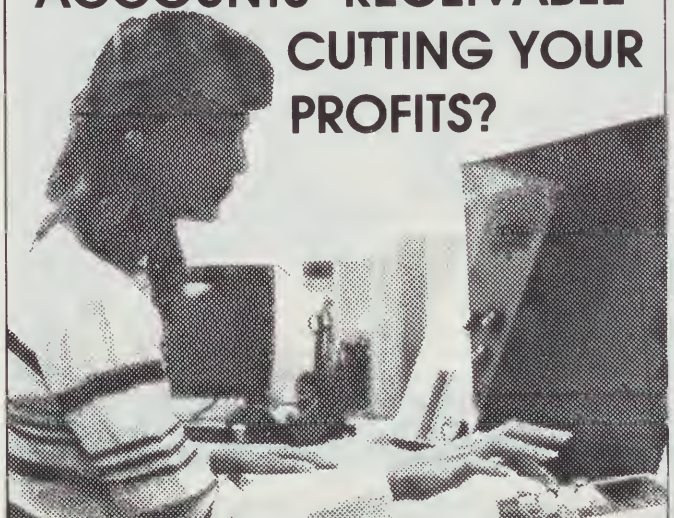
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Miscellaneous Meetings

Sep 20 Eastern Shore Oncology Conference, sponsored by the American Cancer Society and Peninsula General Hospital Medical Center, 5 to 9 p.m., Wicomico Youth and Civic Center, Salisbury. 4 Cat I credits; info: 301-749-1624.

Sep 21 Fall Meeting of the American College of Surgeons, Uniformed Service University of Health Sciences, 4301 Jones Ridge Road, Bethesda, MD 20814. Begins at 9 a.m.; 3 CME credits. Info: William G. Armiger MD 301-646-3226.

Sep 21 Prescription for the Planet in the Nuclear Age, sponsored by the Delaware Academy of Medicine and Physicians for Social Responsibility, Delaware Chapter: Grand Opera House, Wilmington: 7 Cat I credits of Physician's Recognition Award of the AMA. Info: Physicians for Social Responsibility/Delaware, P.O. Box 7588, Newark, DE 19714 (302-454-3600).

Sep 27 Clinical Problems of the Aged presented by the Department of Medical Education, Suburban Hospital, 8600 Old Georgetown Rd., Bethesda, MD 20814. Info: 301-530-3869.

Oct 4 Selected Topics in Pediatrics, sponsored by Eastern Virginia Medical School, Children's Hospital of the King's Daughters, Norfolk, VA. Info: J. E. Shelton MD, Children's Hospital of the King's Daughters, 800 West Olney Road, Norfolk, VA 23507 (804-628-3798).

Oct 5 Advances in Human Genetics and Reproduction, organized by the Genetics & IVF Institute and the Fairfax Hospital. Crystal Gateway Marriott, Arlington, VA. CME Cat I credit; info: 703-698-3101.

Oct 16 Up-Date in Therapeutics, Cross Keys Inn, Baltimore, sponsored by the Department of Medicine and the Department of Medical Education, Bon Secours Hospital. 7 CME Cat I credits. Info: 301-361-3027.

Oct 18 Using Your Computer to Keep Current, presented by the Department of Medical Education, Suburban Hospital, 8600 Old Georgetown Rd., Bethesda, MD 20814. Info: 301-530-3869.

Oct 25–27 Health Care—Impact of Government and Corporate America, a national seminar sponsored by the American College of Utilization Review Physicians (ACURP) in Washington, DC. 10 Cat I credits from ACURP. Each day will have a specific theme: Friday, "Government's Impact on Health Care"; Saturday, "The Physician's Quest to Assure Quality Health Care"; and Sunday, "How the Cost Containment Pressures of Corporate American are Effecting Health Care." Info: ACURP, 30 N. 36th St., Camp Hill, PA 17011 (717-737-5660).

Nov 1–2 Training for Health: Prevention and Treatment of Common Athletic Injuries, Philadelphia, PA, sponsored by Trieber Assoc., Inc., and Southern Medical Assoc. Fee $350 (including hotel); info: Trieber Assoc., Inc., 9407 Jodale Rd., Randallstown, MD 21113 (301-655-5062).

Nov 5–8 Fall Meeting American Academy of Clinical Anesthesiologists, Atlantic City, New Jersey, Resorts International Hotel. Info: AACA, POB 11691, Knoxville, TN 37939 (615-588-6279).

Nov 14–15 Pediatric Head Injury: Innovative Approaches to Rehabilitation, presented by the Rehabilitation Institute of Pittsburgh. Info: The Rehabilitation Institute of Pittsburgh, 6301 Northumberland St., Pittsburgh, PA 15217 (412-521-9000, ext. 325 or 343).

Nov 20–22 8th National Trauma Symposium-Making a Difference, Sheraton Inner Harbor, Baltimore.

Dec 4–6 Recent Advances in Clinical Medicine. Info: Chairman, Department of Medicine, Box 466, Charlottesville, VA 22908 (804-924-2042).

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Taylor Manor Hospital CME Lectures

All lectures at 3 p.m. in the Psychiatric Center at Taylor Manor Hospital, Ellicott City, MD unless otherwise indicated. Info: Taylor Manor Hospital, College Ave., Ellicott City, MD 21043 (301-465-3322).

Oct 16 Diagnostic Confusion Over Depressive Disorder in Adolescents

Nov 13 Family Therapy for Behavior Disordered Adolescents.

Dec 4 New Female Adult Developmental Theory: A Critique of the State of the Art

• • •

The Johns Hopkins Medical Institution

All courses at the Turner Auditorium Building unless otherwise indicated. Sponsored Continued Education Activities for 1985–86. Info: Office of Continuing Education, 720 Rutland Ave., Turner Auditorium, Baltimore, MD 21205 (301-955-5880).

Sep 20–21 Rheumatology Update, 1985 sponsored by The Johns Hopkins University School of Medicine, The Maryland Society for Rheumatic Diseases, Maryland Lupus Foundation, and The Arthritis Foundation, Maryland Chapter. Fee: $100 physicians, $50 arthritis health professions, $50 nurses; 1 AMA Cat I credit.

Oct 3–4 The Health Care Provider: Infectious and Reproductive Hazards, Medical, Legal, and Ethical Issues, at the School of Hygiene and Public Health, Department of Environmental Health Sciences, Baltimore. Info: 301-955-2609.

Oct 3–5 Eleventh Annual Topics in Gastroenterology and Liver Disease. Fee: $300 physicians, $150 residents and fellows; application has been made for 20 AMA Cat I credits.

Oct 18–19 Topics in Allergy and Otolaryngology, The Asthma and Allergy Foundation, Maryland Chapter, cosponsor. Fee: $200; 12.5 CME credits. Info: J. Ryan 301-955-6046.

Oct 21–25 Twenty-seventh Annual Emil Novak Memorial Course: Gynecology, Gynecological Pathology, and High-Risk Obstetrics. Fee: $550 regular, $400 residents; 47 3/4 AMA Cat I credits.

Nov 1 Diabetic Retinopathy. Fee: $150 physicians, $75 residents and fellows; 9.5 AMA Cat I. Info: J. Ryan 301-955-6046.

Nov 15 Progress in Pediatrics 1985. Fee: $80 physicians, $40 residents; 11 AMA Cat I credits. Info: J. Ryan 301-955-6046.

Nov 16 Seminar on Toxicologic Emergencies, sponsored by the Department of Emergency Medicine and Maryland Poison Control Center. Fee: $55; 6 AMA, ACEP and other appropriate credit pending.

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The Department of Radiology and Radiological Science, offers several courses in abdominal and obstetrical ultrasound: courses scheduled Jan 14 to Dec 6, 1985. Info: Joan Mosmiller, Department of Radiology (301-955-8450).

Basic Practicum Sep 23–27. Fee: $460; 40 AMA Cat I credits.

Advanced Practicum Dec 2–6. Fee $460; 40 AMA Cat I credits.

Visiting Physicians offered weekly throughout the year for experience in the lab and participation in reading sessions. By appointment. Fee: $460; 40 AMA Cat I credits.

Advanced Obstetrics and Gynecology course designed for obstetricians who have been using real time ultrasound. Nov 18–20. Fee: $325; 24 AMA Cat I credits.

The Johns Hopkins Medical Ground Rounds. Accredited audiovisual subscription program for the practicing physician. 40 AMA Cat I credits/year. Write to the Johns Hopkins University School of Medicine, Office of Continuing Education, 720 Rutland Ave., Baltimore, MD 21205 (301-955-3988).

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Application and completed preregistration is advised ASAP: completed preregistration must be done before March 28, 1986, unless by special arrangement. Info: John K. Frost MD, 604 Pathology Bldg, The Johns Hopkins Hospital, Baltimore, MD 21205, USA.

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University of Maryland School of Medicine

CME Courses: For each course additional information may be obtained by contacting Program of Continuing Education, University of Maryland School of Medicine, Room 300, MSTF, 10 South Pine St., Baltimore, MD 21201 (301-528-3956).

Sep 26–27 CO_2 Lasers for Otolaryngologists and Allied Specialties. UMAB Campus. Limited to 20 physicians. Fee: $675; 12.75 AMA Cat I credits.

Nov 13 Practical Psychopharmacologic Management of Anxiety Syndrome. International Hotel at BWI. Fee: $40; 6 AMA Cat I Credits.

Nov 21–23 Symposium on Obstetrics and Gynecology: An Up-to-Date Postgraduate Course. Baltimore Plaza Hotel. Fee: $150; 13 AMA Cat I credits.

Nov 23 Higher Cortical Function and Dysfunction in the Elderly. Hyatt Regency, Baltimore. Fee: TBA; 6 AMA Cat I credits.

Dec 6 Hypertension Symposium. UMAB Campus. Fee: TBA; 6 AMA Cat I credits.

Dec 6–7 Office Management of the Injured Patient. Baltimore Plaza Hotel. Fee: $125; 10 AMA Cat I credits.

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Advertisers' Index

Allstate Leasing ... 913
Archway Ford ... 922
Associated Speech & Langauge Services ... 930
The Atrium at Greenspring ... 904
Ayerst Laboratories ... 865
The Bank of Baltimore ... 838
Biophotographic Service ... 930
Blue Cross & Blue Shield of Md., Inc. ... 834
Business Automation, Inc. ... 858
Campbell Laboratories, Inc. ... 899
The Carousel Hotel ... 906
Cellular One ... 850
Closet Masters ... 923
Consultative Examinations, Inc. ... 928
Curtis 1000 ... 845
Davis Leasing Corp. ... 904
Diagnostic Assay Services, Inc. ... 835
Elcomp Systems ... 837
Elkridge Estates ... 931
Epic Residential Network, Inc. ... 924
Family Home Care ... 930
John M.T. Finney, III, Realtor® ... 922
Foto Finishers, Inc. ... 930
GMC Truck Center ... 924
Gordon & Heneson PA ... 921
Grady Management, Inc. ... 872
Drs. Groover, Christie & Merritt, Partnership ... 928
Gundry Hospital ... 858
Heron Harbour Isle ... 849
Hidden Brook Treatment Center ... 882
Intracare Corp. ... 852
JBA Leasing ... 920
Jerry's Toyota ... 896
King's Grant ... 832
Kipp & Son ... 840
Koons Porsche Audi ... 842
Eli Lilly ... 836
Marion Laboratories ... 885
Maryland Army National Guard ... 858
Maryland Office Systems ... 921
Maryland Medical Laboratory, Inc. ... 831
M-D Answering Service ... 906
Med-Chi ... 923
Medical Mutual Liability ... Cover 2
Medical Personnel Pool ... 861
Meridian Healthcare ... 864
Michaelson Motors, Inc. ... 923
Micro Computer Associates, Inc. ... 920
Mid-Atlantic Vision Service Plan ... 878
Moorings on the Magothy ... 913
Mountain Manor Treatment Center ... 899
Multicom Incorporated ... 913
National Credit Management Corp. ... 924
Old Court Nursing Center ... 873
Parke-Davis ... 915
Physician and Sportsmedicine ... 843
physician's resource network ... 930
PM Baltimore ... 921
Postgraduate Medicine ... 843
R & H Motor Cars Ltd. ... 895
Roche Laboratories ... Covers 3 & 4
W. James Schiller & Co. PA ... 861
Schumacher & Seiler Inc. ... 846
Sheppard & Enoch Pratt Hospital ... 857
Sheraton Inner Harbor ... 839
South Baltimore General Hospital ... 928
Staff Builders ... 878
T.J. Stratton Co., Inc. ... 862
Sunspace Design Studio ... 923
Tekmatix NA ... 928
Towson Valley Motors ... 932
Uncle Lee's Restaurant ... 922
Union Trust Co. ... 841
Unique Design, Inc. ... 895
Upjohn Company ... 887
U.S. Army ... 884
U.S. Army Medical Reserve ... 844
VNA ... 906
Van Dyke & Bacon Shoes ... 922

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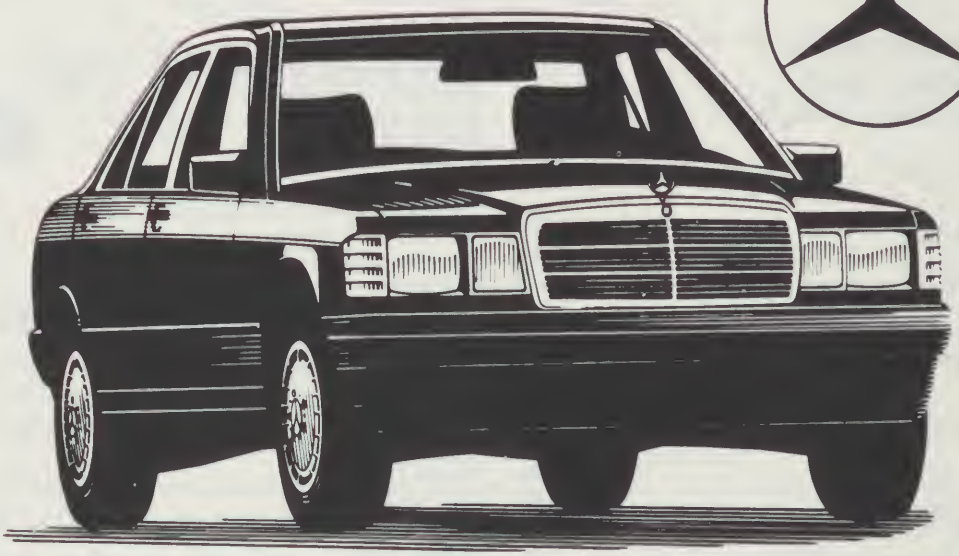
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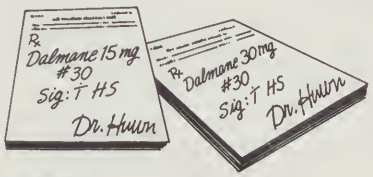
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Executive Director's Newsletter 949
Hotline Numbers 996, 1028
Physician Placement Service 996
Change of Address Form 1002
Information for Authors 1011
Doctors Take Note 1015
Medicolegal Hotline 1029
Classified Ads 1031
Advertisers' Index 1033

ARTICLES

Healthy Mothers, Healthy Babies—Albert M. Antlitz MD and Carmine M. Valente PhD 971

"Life-style" Factors and Pregnancy Outcome—Beverly S. Raff PhD 975

Patient Motivation During Pregnancy—Marlyn D. Boyd PhD 977

Smoking and Healthy Pregnancy: Now Is the Time to Quit—Paul R. Feldman MD 982

Alcohol and Drug Use in Pregnancy: A Case for Management—Carol Lynn Mullins MD and Preston Mann Gazaway, III, MD ... 991

Influencing Pregnancy Outcome Through Nutrition and Dietary Changes—Diane L. Dimperio MA and Charles S. Mahan MD 997

Behavioral Risks and Pregnancy Outcome: Attitudes and Practices of OB/GYNs—Carmine M. Valente PhD; Jeffery Sobal PhD; Herbert L. Muncie, Jr., MD; David M. Levine MD; Albert M. Antlitz MD; and Bruce R. DeForge MA 1003

Preterm Delivery and Patient Education—David A. Nagey MD and Annelies Zachary MD 1006

Resources Available from the March of Dimes—Beverly S. Raff PhD 1008

DEPARTMENTS

Disease Control and Epidemiology Newsletter 955

Improving pregnancy outcome and reducing infant mortality will require some gravidas to modify their behavior. Physicians can have the greatest impact on those women by focusing on the following risk factors related to the outcome of pregnancy: diet and nutrition; and tobacco, alcohol, and drug use. Articles beginning on page 971 represent a broad range of facts and opinion about promoting Healthy Mothers, Healthy Babies. Guest editors are Albert M. Antlitz MD and Carmine M. Valente PhD. *Cover logo* used with permission of the Healthy Mothers/Healthy Babies Coalition.

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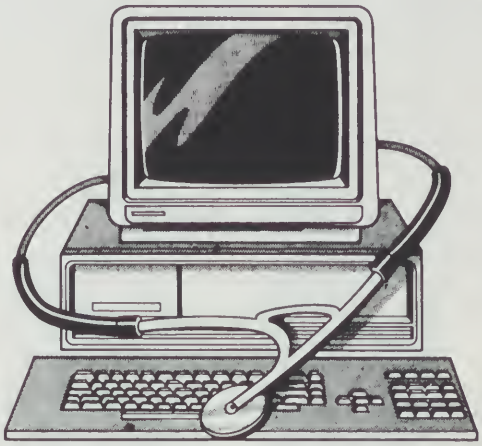
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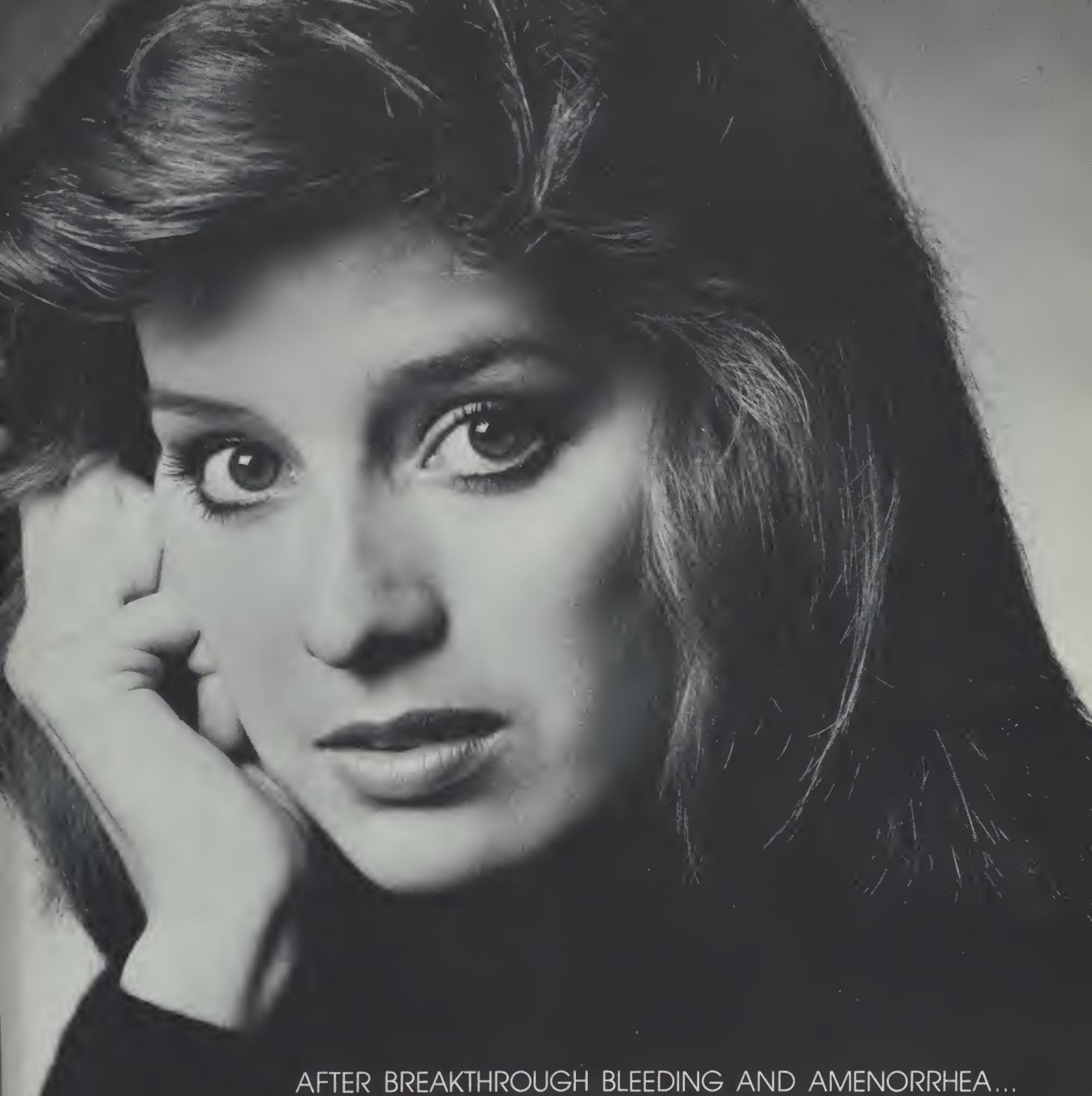
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(1 mg norethindrone acetate and 50 mcg ethinyl estradiol tablets, USP) 1/50

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See next page for brief summary of prescribing information.

Brief Summary of Prescribing Information
NORLESTRIN® (norethindrone acetate and ethinyl estradiol tablets, USP)

See section under **Special Notes on Administration and HOW SUPPLIED.**
Before prescribing, please see full prescribing information. A Brief Summary follows

DESCRIPTION
Norlestrin Products are progestogen-estrogen combinations

INDICATIONS AND USAGE
Norlestrin Products are indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

In clinical trials with Norlestrin 1/50 involving 25,983 therapy cycles, there was a pregnancy rate of 0.05 per 100 woman-years; in clinical trials with Norlestrin 2.5/50 involving 96,388 cycles, there was a pregnancy rate of 0.22 per 100 woman-years.

Dose-Related Risk of Thromboembolism from Oral Contraceptives: Studies have shown a positive association between the dose of estrogens in oral contraceptives and the risk of thromboembolism. It is prudent and in keeping with good principles of therapeutics to minimize exposure to estrogen. The oral contraceptive prescribed for any given patient should be that product which contains the least amount of estrogen that is compatible with an acceptable pregnancy rate and patient acceptance.

CONTRAINDICATIONS
1. Thrombophlebitis or thromboembolic disorders
2. A past history of deep-vein thrombophlebitis or thromboembolic disorders
3. Cerebral vascular or coronary artery disease
4. Known or suspected carcinoma of the breast
5. Known or suspected estrogen-dependent neoplasia
6. Undiagnosed abnormal genital bleeding
7. Known or suspected pregnancy (See WARNING No. 5)
8. Benign or malignant liver tumor which developed during the use of oral contraceptives or other estrogen-containing products.

WARNINGS

Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke.

The use of oral contraceptives is associated with increased risk of several serious conditions including thromboembolism, stroke, myocardial infarction, hepatic adenoma, gallbladder disease, and hypertension. Practitioners prescribing oral contraceptives should be familiar with the following information relating to these risks.

1. *Thromboembolic Disorders and Other Vascular Problems.* An increased risk of thromboembolic and thrombotic disease associated with the use of oral contraceptives is well-established. Studies have demonstrated an increased risk of fatal and nonfatal venous thromboembolism and stroke, both hemorrhagic and thrombotic.

Cerebrovascular Disorders: In a collaborative study in women with and without predisposing causes, it was estimated that the risk of hemorrhagic stroke was 2.0 times greater in users than nonusers, and the risk of thrombotic stroke was 4.0 to 9.5 times greater.

Myocardial Infarction: An increased risk of myocardial infarction associated with oral contraceptives has been reported confirming a previously suspected association. These studies found that the greater the number of underlying risk factors (cigarette smoking, hypertension, hypercholesterolemia, obesity, diabetes, history of preeclamptic toxemia) for coronary artery disease, the higher the risk of developing myocardial infarction, regardless of whether the patient was an oral contraceptive user or not. Oral contraceptives, however, were found to be a clear additional risk factor.

It has been estimated that users who do not smoke (smoking is considered a major predisposing condition to myocardial infarction) are about twice as likely to have a fatal myocardial infarction as nonusers who do not smoke. Oral contraceptive users who are smokers have about a fivefold increased risk of fatal infarction compared to users who do not smoke, but about a tenfold to twelvefold increased risk compared to nonusers who do not smoke. The amount of smoking is also an important factor.

Risk of Dose: In an analysis of data, British investigators concluded that the risk of thromboembolism, including coronary thrombosis, is directly related to the dose of estrogen used in oral contraceptives; however, the quantity of estrogen may not be the sole factor involved.

Persistence of Risk: Two studies have suggested that an increased risk may persist for as long as 6 years after discontinuation of oral contraceptive use for cerebrovascular disease and 9 years for myocardial infarction. In addition, a prospective study suggested the persistence of risk for subarachnoid hemorrhage.

Estimate of Excess Mortality from Circulatory Diseases: The risk of diseases of the circulatory system is concentrated in older women, in those with a long duration of use, and in cigarette smokers.

A study of available data from a variety of sources concluded that the mortality associated with all methods of birth control is low and below that associated with childbirth, with the exception of oral contraceptives in women over 40 who smoke.

The risk of thromboembolic and thrombotic diseases associated with oral contraceptives increases with age after approximately age 30 and, for myocardial infarction, is further increased by hypertension, hypercholesterolemia, obesity, diabetes, or history of preeclamptic toxemia, and especially by cigarette smoking.

The physician and the patient should be alert to the earliest manifestations of thromboembolic and thrombotic disorders. Should any occur or be suspected, the drug should be discontinued immediately.

A fourfold to sixfold increased risk of postsurgery thromboembolic complications has been reported in users. If feasible, oral contraceptives should be discontinued at least four weeks before surgery of a type associated with an increased risk of thromboembolism or prolonged immobilization.

2. *Ocular Lesions.* Neuro-ocular lesions, such as optic neuritis or retinal thrombosis, have been associated with the use of oral contraceptives. Discontinue the oral contraceptive if there is unexplained sudden or gradual, partial, or complete loss of vision; onset of proptosis or diplopia; papilledema; or retinal vascular lesions.

3. *Carcinoma.* Long-term continuous administration of estrogen in certain animal species increases the frequency of carcinoma of the breast, cervix, vagina, and liver.

In humans, an increased risk of endometrial carcinoma associated with the prolonged use of exogenous estrogen in postmenopausal women has been reported. However, there is no evidence suggesting increased risk of endometrial cancer in users of conventional combination or progestogen-only oral contraceptives.

Studies found no evidence of increase in breast cancer in women taking oral contraceptives; however, an excess risk in users with documented benign breast disease was reported.

There is no confirmed evidence of an increased risk of cancer associated with oral contraceptives. Close clinical surveillance of users is, nevertheless, essential. In cases of undiagnosed persistent or recurrent abnormal vaginal bleeding, appropriate diagnostic measures should be taken to rule out malignancy. Women with a strong family history of breast cancer, or who have breast nodules, fibrocystic disease, or abnormal mammograms, should be monitored with particular care.

4. *Hepatic Tumors.* Benign hepatic adenomas have been found to be associated with oral contraceptives. Because hepatic adenomas may rupture and may cause death through intra-abdominal hemorrhage, they should be considered in women presenting abdominal pain and tenderness, abdominal mass, or shock.

A few cases of hepatocellular carcinoma have been reported in women taking oral contraceptives. The relationship of these drugs to this type of malignancy is not known at this time.

5. *Usage in or Immediately Preceding Pregnancy; Birth Defects in Offspring, and Malignancy in Female Offspring.* During early pregnancy, female sex hormones may seriously damage the offspring.

An increased risk of congenital anomalies, including heart defects and limb defects, has been reported with the use of oral contraceptives in pregnancy.

There is some evidence that triploidy and possible other types of polyploidy are increased among abortuses from women who become pregnant soon after ceasing oral contraceptives.

Pregnancy should be ruled out before continuing an oral contraceptive in any patient who has missed two consecutive menstrual periods. If the patient has not adhered to the schedule, the possibility of pregnancy should be considered at the time of the first missed period, and oral contraceptives should be withheld until pregnancy has been ruled out. If pregnancy is confirmed, the patient should be apprised of the potential risks to the fetus and the advisability of continuation of the pregnancy should be discussed.

Women who discontinue oral contraceptives with the intent of becoming pregnant should use an alternate form of contraception for a period of time before attempting to conceive.

Administration of progestogen-only or progestogen-estrogen combinations to induce withdrawal bleeding should not be used as a test of pregnancy.

6. *Gallbladder Disease.* Studies report an increased risk of surgically confirmed gallbladder disease in users of oral contraceptives.

7. *Carbohydrate and Lipid Metabolic Effects.* Because decreased glucose tolerance has been observed in a significant percentage of patients, prediabetic and diabetic patients should be carefully observed while receiving oral contraceptives.

An increase in triglycerides and total phospholipids has been observed.

8. *Elevated Blood Pressure.* An increase in blood pressure has been reported in patients receiving oral contraceptives. The prevalence in users increases with longer exposure. Age is also strongly correlated with development of hypertension. Women who previously have had hypertension during pregnancy may be more likely to develop elevation of blood pressure.

9. *Headache.* Onset or exacerbation of migraine or development of headache of a new pattern which is recurrent, persistent, or severe, requires discontinuation of oral contraceptives.

10. *Bleeding Irregularities.* Breakthrough bleeding, spotting, and amenorrhea are frequent reasons for patients discontinuing oral contraceptives. In breakthrough bleeding, nonfunctional causes should be borne in mind. In undiagnosed abnormal bleeding from the vagina, adequate diagnostic measures are indicated to rule out pregnancy or malignancy.

Women with a past history of oligomenorrhea or secondary amenorrhea or young women without regular cycles should be advised that they may have a tendency to remain anovulatory or to become amenorrheic after discontinuation of oral contraceptives.

11. *Ectopic Pregnancy.* Ectopic as well as intrauterine pregnancy may occur in contraceptive failures.

12. *Breast-Feeding.* Oral contraceptives may interfere with lactation. Furthermore, a small fraction of the hormonal agents in oral contraceptives has been identified in the milk of mothers receiving these drugs.

PRECAUTIONS
1. A complete medical and family history should be taken prior to the initiation of oral contraceptives. The pretreatment and periodic physical examinations should include special reference to blood pressure, breasts, abdomen, and pelvic organs, including Papanicolaou smear and relevant laboratory tests. As a general rule, oral contraceptives should not be prescribed for longer than one year without another examination.
2. Preexisting uterine leiomyomata may increase in size.
3. Patients with a history of psychic depression should be carefully observed and the drug discontinued if depression recurs to a serious degree.
4. Oral contraceptives may cause fluid retention and should be prescribed with caution, and only with careful monitoring, in patients with conditions which might be aggravated.
5. Patients with a past history of jaundice during pregnancy have an increased risk of recurrence of jaundice. If jaundice develops, the medication should be discontinued.
6. Steroid hormones may be poorly metabolized and should be administered with caution in patients with impaired liver function.
7. Users may have disturbances in normal tryptophan metabolism, which may result in a relative pyridoxine deficiency.
8. Serum folate levels may be depressed.
9. The pathologist should be advised of oral contraceptive therapy when relevant specimens are submitted.
10. Certain endocrine and liver function tests and blood components may be affected. (a) Increased sulfobromophthalein retention. (b) Increased prothrombin and factors VII, VIII, IX, and X; decreased antithrombin 3; increased norepinephrine-induced platelet aggregability. (c) Increased thyroid-binding globulin (TBG) leading to increased circulating total thyroid hormone. (d) Decreased pregnanediol excretion. (e) Reduced response to metyrapone test.

Drug Interactions: Reduced efficacy and increased incidence of breakthrough bleeding have been associated with concomitant use of rifampin. A similar association has been suggested with barbiturates, phenylbutazone, phenytoin sodium, tetracycline, and ampicillin.

ADVERSE REACTIONS
An increased risk of the following serious adverse reactions has been associated with oral contraceptives: thrombophlebitis; pulmonary embolism; coronary thrombosis; cerebral thrombosis; cerebral hemorrhage; hypertension; gallbladder disease; benign hepatomas; congenital anomalies.

There is evidence of an association between the following conditions and the use of oral contraceptives, although additional confirmatory studies are needed: mesenteric thrombosis; neuro-ocular lesions, eg, retinal thrombosis and optic neuritis.

The following adverse reactions have been reported in patients receiving oral contraceptives and are believed to be drug related: nausea and/or vomiting, usually the most common adverse reactions, occur in approximately 10% or less of patients during the first cycle. Other reactions, as a general rule, are seen much less frequently or only occasionally: gastrointestinal symptoms; breakthrough bleeding; spotting; change in menstrual flow; dysmenorrhea; amenorrhea during and after treatment; temporary infertility after discontinuance of treatment; edema; chloasma or melasma; breast changes; change in weight; change in cervical erosion and cervical secretion; possible diminution in lactation when given immediately postpartum; cholestatic jaundice; migraine; increase in size of uterine leiomyomata; rash (allergic); mental depression; reduced tolerance to carbohydrates; vaginal candidiasis; change in corneal curvature; intolerance to contact lenses.

The following adverse reactions have been reported and the association has been neither confirmed nor refuted: premenstrual-like syndrome; cataracts; changes in libido; chorea; changes in appetite; cystitis-like syndrome; headache; nervousness; dizziness; hirsutism; loss of scalp hair; erythema multiforme; erythema nodosum; hemorrhagic eruption; vaginitis; porphyria.

Special Notes on Administration
Menstruation usually begins two or three days, but may begin as late as the fourth or fifth day, after discontinuing medication.

After several months on treatment, bleeding may be reduced to a point of virtual absence; reduced flow may be a result of medication and not indicative of pregnancy.

HOW SUPPLIED
Norlestrin [21] 1/50 is available in compacts each containing 21 tablets. Each tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

Norlestrin [21] 2.5/50 is available in compacts each containing 21 tablets. Each tablet contains 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

Norlestrin [Fe] 1/50 is available in compacts each containing 21 yellow tablets and 7 brown tablets. Each yellow tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Each brown tablet contains 75 mg of ferrous fumarate, USP. Available in packages of five compacts and packages of five refills.

Norlestrin [FE] 2.5/50 is available in compacts each containing 21 pink tablets and 7 brown tablets. Each pink tablet contains 2.5 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Each brown tablet contains 75 mg of ferrous fumarate, USP. Available in packages of five compacts and packages of five refills.

Norlestrin [28] 1/50 is available in compacts each containing 21 yellow tablets and 7 white inert tablets. Each yellow tablet contains 1 mg of norethindrone acetate and 50 mcg of ethinyl estradiol. Available in packages of five compacts and packages of five refills.

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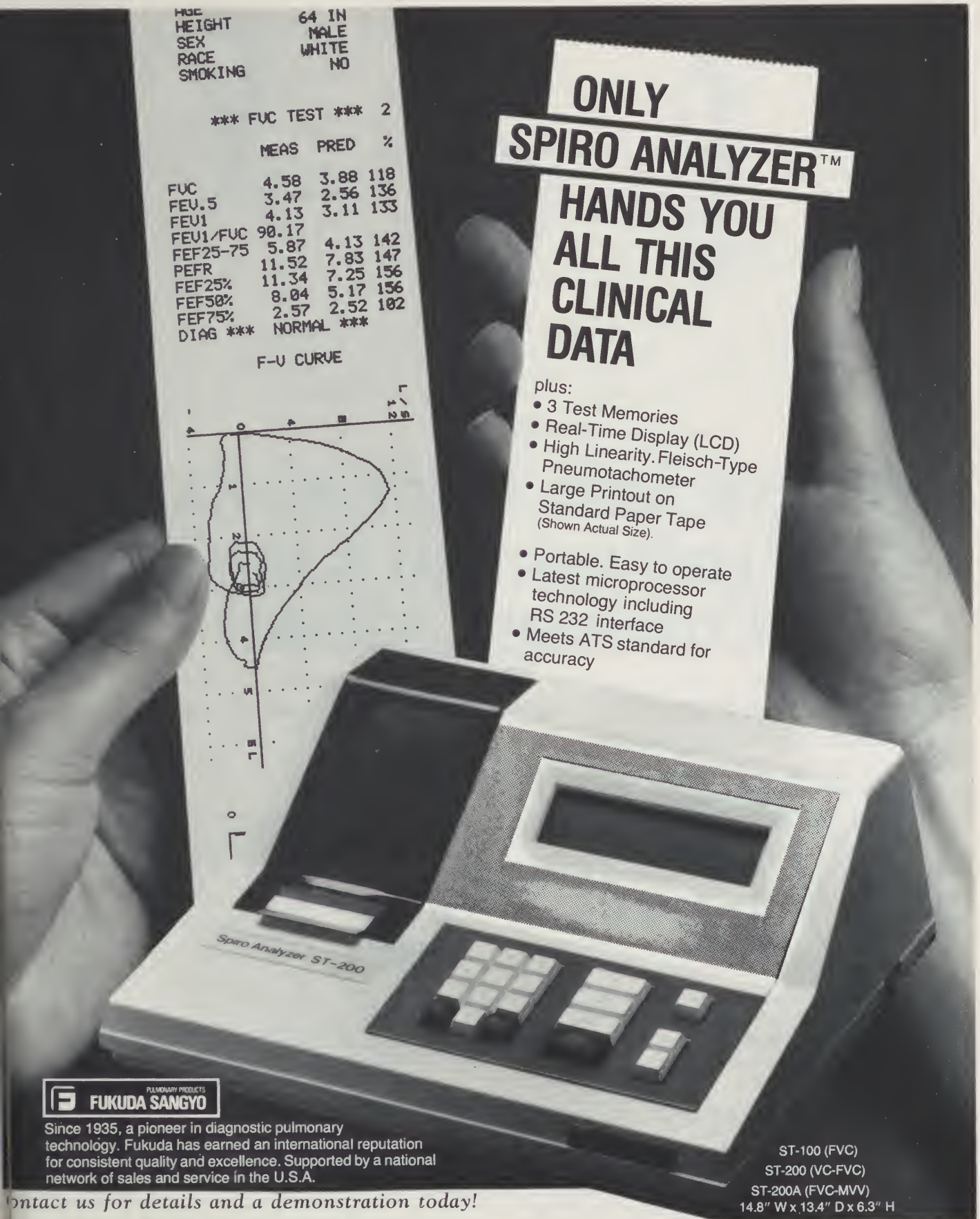
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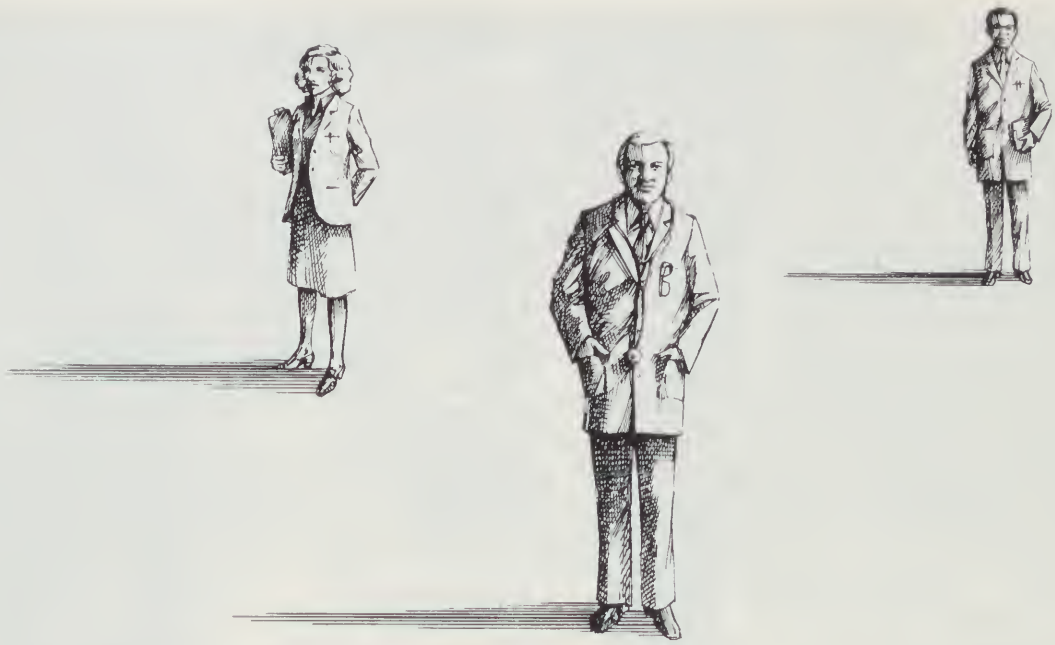
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Executive Director's Newsletter

October 1985

TORT REFORM UPDATE

Faculty spokesman President-elect Donald T. Lewers, MD, addressed the Governor's Task Force on Medical Malpractice Insurance on "Impact of Malpractice Insurance on Health Care Costs and Access" in late September. Dr. Lewers, members of the Commission on Medical Discipline, and the Board of Medical Examiners presented an overview of the peer review and discipline system on October 1.

Specific interest was directed to the effectiveness of the present system and to any weaknesses in the system. Recent publications from the Nader organization have questioned the physician peer review systems in effect throughout the country.

The Faculty was urged to develop specific legislation to deal with the malpractice problem and submit it to the Task Force. Items discussed at the hearing included premium subsidization of high-risk specialties by the state to provide needed medical services to communities, a worker's compensation approach where future medical expenses are guaranteed to the patient exclusive of any award, a method of determining "true negligence," and suggestions for improving the peer review system.

As the Task Force perseveres in its discussions and hearings the Faculty will continue to monitor and participate in the activity.

The Faculty has been urged to ensure that physicians speak with one voice. The Task Force and General Assembly leaders have expressed concerns that the Faculty be the official spokesman for the physicians in Maryland. A divided house with many voices claiming to represent the physician community can result only in chaos or in no action by the General Assembly.

PROFESSIONAL LIABILITY SEMINAR

Last month we announced the Professional Liability Seminar sponsored by Delegate Larry Young (D, 39th District, Baltimore City). The date of the seminar has been changed. THE NEW DATE IS MONDAY, NOVEMBER 25, 1985 AT THE HYATT REGENCY DOWNTOWN.

This seminar will provide an excellent opportunity for your patients and other members of the public to become informed about malpractice issues. For registration information call the Faculty office 1-800-492-1056 (toll-free in Maryland) or 539-0872 in the Baltimore metro area.

LIVING WILL

The 1985 session of the General Assembly enacted legislation to permit patients to sign a "living will" to permit discontinuation of life-sustaining procedures. Patients may begin to ask questions about making a declaration to this effect. Declarations must be placed in the patient's medical record and can be implemented only after the patient is diagnosed by two physicians as being in a terminal condition. A complete summary of the new statute will be in the 1985 Compendium supplement, which should be ready by November.

1986 DUES BILLS

The 1986 dues bills will be in the mail to all members at the beginning of December. Physicians are reminded that payment of dues by January 31, 1986 is necessary to qualify for a legal defense panel, as outlined in the Faculty Bylaws.

All dues and assessments are tax-deductible items for physicians.

RESOLUTIONS DEADLINE

The deadline date for receipt of resolutions for consideration at the 1986 Annual Session of the House of Delegates is

FRIDAY, FEBRUARY 21, 1986

All resolutions must be received in the Faculty office by close of business on that date.

Resolutions must be sponsored by a member or component society of the Faculty, the Council, or committees of the Faculty. A resolution introduced by an individual member must have the endorsement of either one-third of the membership of his component society or 30 members of his component society, whichever is smaller.

MEMBERSHIP DIRECTORY

The Faculty's 1986 Membership Directory will be mailed to all members of the Faculty this month. Individual copies may be purchased at $35, plus $1 for postage and handling. Payment must accompany orders.

John Sargent
Executive Director

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Contact Dr. David Waltos, Admissions Officer, Sheppard and Enoch Pratt Hospital, P.O. Box 6815, Baltimore, Maryland 21204. (301) 823-8200.



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MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE

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OCTOBER 1985

HETEROSEXUAL TRANSMISSION OF HUMAN T-LYMPHOTROPIC VIRUS TYPE III/LYMPHADENOPATHY-ASSOCIATED VIRUS

Acquired immunodeficiency syndrome (AIDS) is caused by a virus that is known to be transmitted through sexual contact and parenteral exposure to blood or blood products and from mother to child during the perinatal period.

In the United States, sexual contact is believed to be the only risk factor for 8,374 (64%) of the 13,061 AIDS cases among adults reported to CDC as of September 16, 1985. These sexual-contact cases include 8,241 homosexual or bisexual men with no other known risk factors for infection and 133 heterosexual men and women.

The heterosexual-contact cases are among persons who denied belonging to known AIDS risk groups, but reported sexual contact with a risk-group member or an AIDS patient of the opposite sex. The proportion of AIDS patients placed in this category has not changed significiantly over time ($p>0.15$). The 133 heterosexual-contact cases include 118 women and 15 men, the majority of whom said they had sexual contact with intravenous (IV) drug abusers.

No risk factors have been identified for HTLV-III/LAV infection in 829 of the total AIDS cases reported to CDC. Of these 829 patients, 344 were born in developing countries where AIDS is known to exist. The remaining 485 cases constitute a proportion of AIDS patients that has not changed significantly over time ($p>0.15$). Of these 485 patients with no identified risk, 99 were available for in-depth interviews. Twenty-three (34%) of the 68 men gave histories of sexual contact with female prostitutes. One (3%) of the 31 women gave a history of prostitution.

Serologic evidence of HTLV-III/LAV infection in female prostitutes has been shown in preliminary studies from several American cities. Of 92 prostitutes tested in Seattle, five (5%) had HTLV-III antibody detected by the enzyme immunoassay (EIA) tests of two manufacturers. In Miami, Florida, 10 (40%) of 25 prostitutes attending an AIDS screening clinic had HTLV-III antibody detected by both EIA and Western blot methods. Eight of the 10 seropositive women reported previous IV drug abuse.

Studies of AIDS patients from several developing countries also indicate that female-to-male sexual transmission of HTLV-III infection occurs in those settings and emphasize the role of female prostitutes in this transmission. In Zaire, the ratio of male-to-female AIDS cases is 1.1:1. A case-control study of heterosexual African men with AIDS or related conditions in Rwanda and Belgium showed a significant association of HTLV-III/LAV infection with a history of contact with prostitutes and with an increased number of female partners per year. A case-control study of Haitian men with AIDS in Miami and New York City showed a significant association of AIDS with a history of prostitute contact and with a history of sexually-transmitted diseases, suggesting that sexual contact may be a major method of transmssion in these heterosexual men.

For persons born in the United States, female-to-male sexual transmission of HTLV-III/LAV has been less evident than male-to-female sexual transmission. The reasons for reported differences in the epidemiologic pattern of HTLV-III/LAV infections in the United states and certain developing countries are not clear. However, there are at least two possible explanations for the paucity of reported male "heterosexual contact" AIDS patients in the United States. First, female-to-male transmission of HTLV-III/LAV may be less efficient than male-to-female transmission, as has been reported for gonococcal infections. Second, the proportion of women among infected persons is relatively small. Of the 2,665 reported heterosexual AIDS patients with known risk factors in the United States, only 647 (24%) are women. The inclusion of 1,427 AIDS cases among bisexual men would further decrease the proportion of women among potential transmitters of infection. If the distribution of HTLV-III/LAV infected persons in the population is similar to the distribution of AIDS patients, infected heterosexual men would outnumber infected women by a ratio of 5:1.

While additional evidence for female-to male transmission of HTLV-III/LAV in the United States is being sought, it would seem prudent to assume that such transmission occurs. In all other sexually-transmitted infections, transmission is bidirectional, and HTLV/III/LAV appears to be spread bidirectionally in other populations. HTLV-III/LAV has been isolated from semen and, presumably, would be present in the menstrual blood and the lymphocytes found in cervical and vaginal secretions of infected women. Attempts to isolate the virus from cervical and vaginal secretions are in progress.

All sexually active persons should realize that their risks of acquiring infection are greatly increased by having sexual intercourse with members of known AIDS risk groups or with persons who are the sexual contacts of risk-group members. Sexually active persons should also recognize that, as with other sexually-transmitted diseases, the greater the number of sexual partners, the greater the risk of possible HTLV-III/LAV

infection. Consistent use of condoms should assist in preventing infection with HTLV-III/LAV, but their efficacy in reducing transmission has not yet been proven.

Editorial Note: Transmission of HTLV-III/LAV from heterosexual men to their female sexual partners has been well established in studies from the United States and elsewhere. Several published reports from the United States describe the occurrence of AIDS in heterosexual couples, where only the male partner had a known AIDS risk factor. A study in Rwanda and Belgium described AIDS or related conditions in 42 African women, including 10 prostitutes who denied IV drug abuse.

SOURCE: Morbidity and Mortality Weekly Report (MMWR), Centers for Disease Control (CDC), Atlanta, Georgia, September 20, 1985/Vol. 34/No. 37.

TETRACYCLINE-RESISTANT NEISSERIA GONORRHOEAE--

Since February 1985, CDC has identified 12 isolates of Neisseria gonorrhoeae that have high-level resistance to tetracycline (minimal inhibition concentration (MIC) 24-32 μg/ml) but are susceptible to penicillin. This high level of tetracycline resistance appears to be a new phenomenon.

Tetracycline resistance has usually been associated with penicillinase-producing strains (PPNG) and with chromosomally resistant N. gonorrhoeae (CMRNG). Strains exhibiting moderate levels of tetracycline resistance (MIC 1-8 μg/ml) have been noted previously. This type of resistance is thought to result from additive effects of mutations at three independent genetic loci. However, the inability of the TRNG strains cited in this report to function as donors of tetracycline resistance strongly suggests that this is a new type of resistance and does not result from previously described genetic determinants. Although all TRNG isolates to date have been sensitive to penicillin, preliminary data indicate that they may have the capability to acquire and maintain a B-lactamase plasmid.

The magnitude of the tetracycline MICs reported here, and their association with treatment failures, raises public health concerns, since tetracycline (minocycline, doxycycline) is sometimes used as the sole therapy for gonococcal genital infections and as neonatal prophylaxis for opthalmia neonatorum. Studies are underway to determine the tetracycline resistance in Maryland.

In light of the resistance to tetracycline, CDC strongly urges that all positive test-of-cure cultures be screened for tetracycline resistance by disk diffusion in addition to recommended procedures for PPNG and CMRNG testing. All gonococcal isolates with an inhibitory zone of less than 30 mm to a 30 μg tetracycline disc on supplemented chocolate agar should be submitted to a reference laboratroy for confirmation by agar dilution techniques. The 1985 CDC Sexually-Transmitted Disease Treatment Guidelines will emphasize that tetracycline (minocycline, doxycycline) therapy alone should be used only in patients with reported penicillin allergy. These patients should be strongly encouraged to return for a posttreatment evaluation.

Source: Morbidity and Mortality Weekly Report (MMWR), Centers for Disease Control (CDC), September 20, 1985/vol. 34/No. 37.

AIDS CASES REPORTED TO MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE FROM 1979 THROUGH 8/31/85

PLACE OF RESIDENCE	CASES	DEATHS
BALTIMORE CITY	79	39
SUBURBAN BALTO. Anne Arundel Co. Baltimore Co. Carroll Co. Harford Co Howard Co.	26	13
METRO-BALTIMORE (SUB-TOTAL)	105	52
SUBURBAN WASHINGTON, D.C. Calvert Co. Charles Co. Frederick Co. Montgomery Co. Pr. George's Co. St. Mary's Co.	90	53
EASTERN SHORE	11	7
WESTERN, MD.	1	1
MARYLAND STATE TOTAL	207	113

MARYLAND AIDS CASES BY YEAR

	CASES	DEATHS	STATUS UNKNOWN
1979-'81	4	4	0
1982	6	6	0
1983	25	21	2
1984	67	47	0
1985 YTD	105	35	0
TOTAL-207		113	2

CENTERS FOR DISEASE CONTROL
NATIONAL STATISICS AS OF 9/2/85

REPORTED CASES	12,932
DEATHS	6,481

SCOTT H. STAMFORD
AIDS PROGRAM COORDINATOR
OFFICE OF DISEASE CONTROL
AND EPIDEMIOLOGY
PHONE: (301) 225-6711

GENDER	CASES	PERCENT
MALE	188	91%
FEMALE	19	9%

ETHNIC/RACE BKG.		
WHITE	89	43%
BLACK	111	54%
HISPANIC	7	3%
OTHER	0	0%
TOTAL	207	100%

AGE GROUP		
0-12	2	1%
13-19	1	1%
20-29	38	18%
30-39	95	46%
40-49	48	23%
Over 50	23	11%
TOTAL	207	100%

METRO-D.C. STATISTICS

RESIDENCE	CASES	DEATHS
Wash. D.C.	219	116
VA. SUBURBS	74	34
MD. SUBURBS	90	53
METRO-D.C.	383	203



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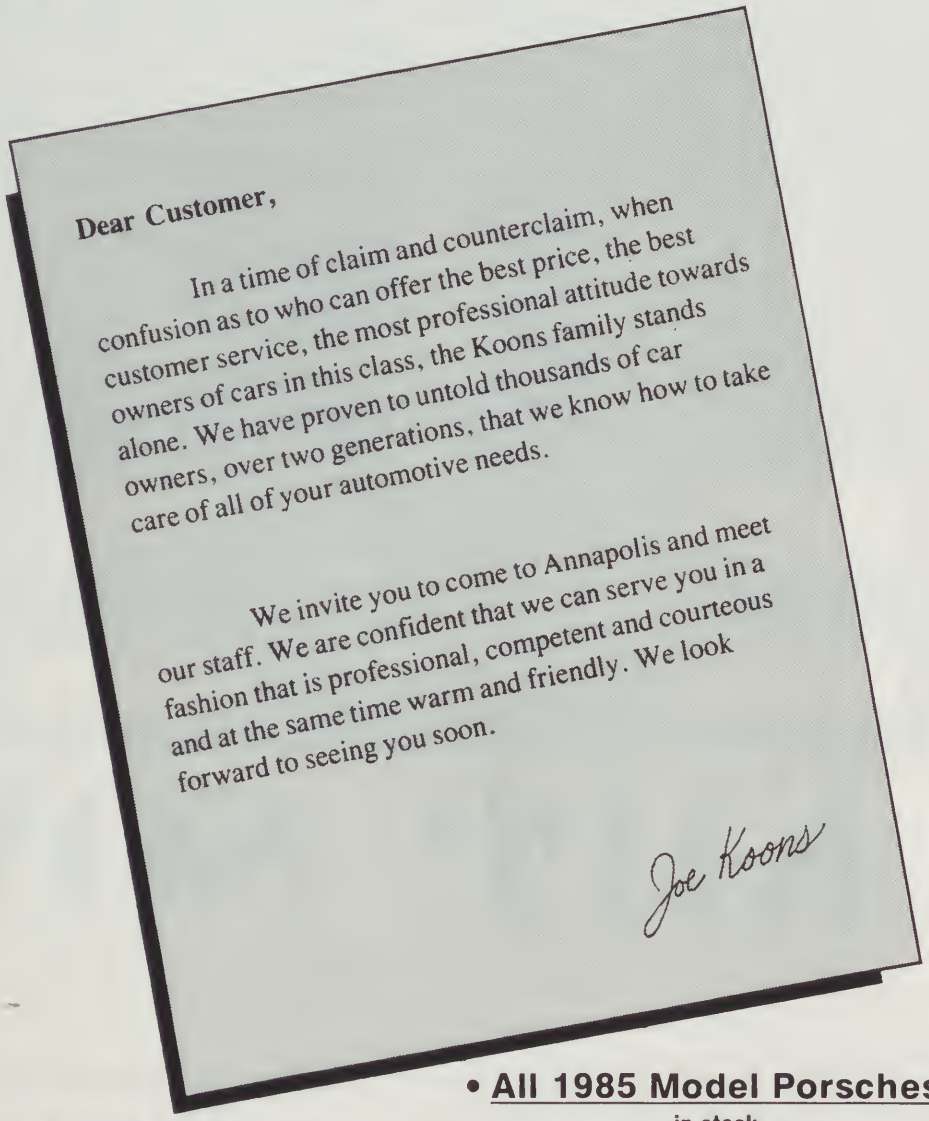
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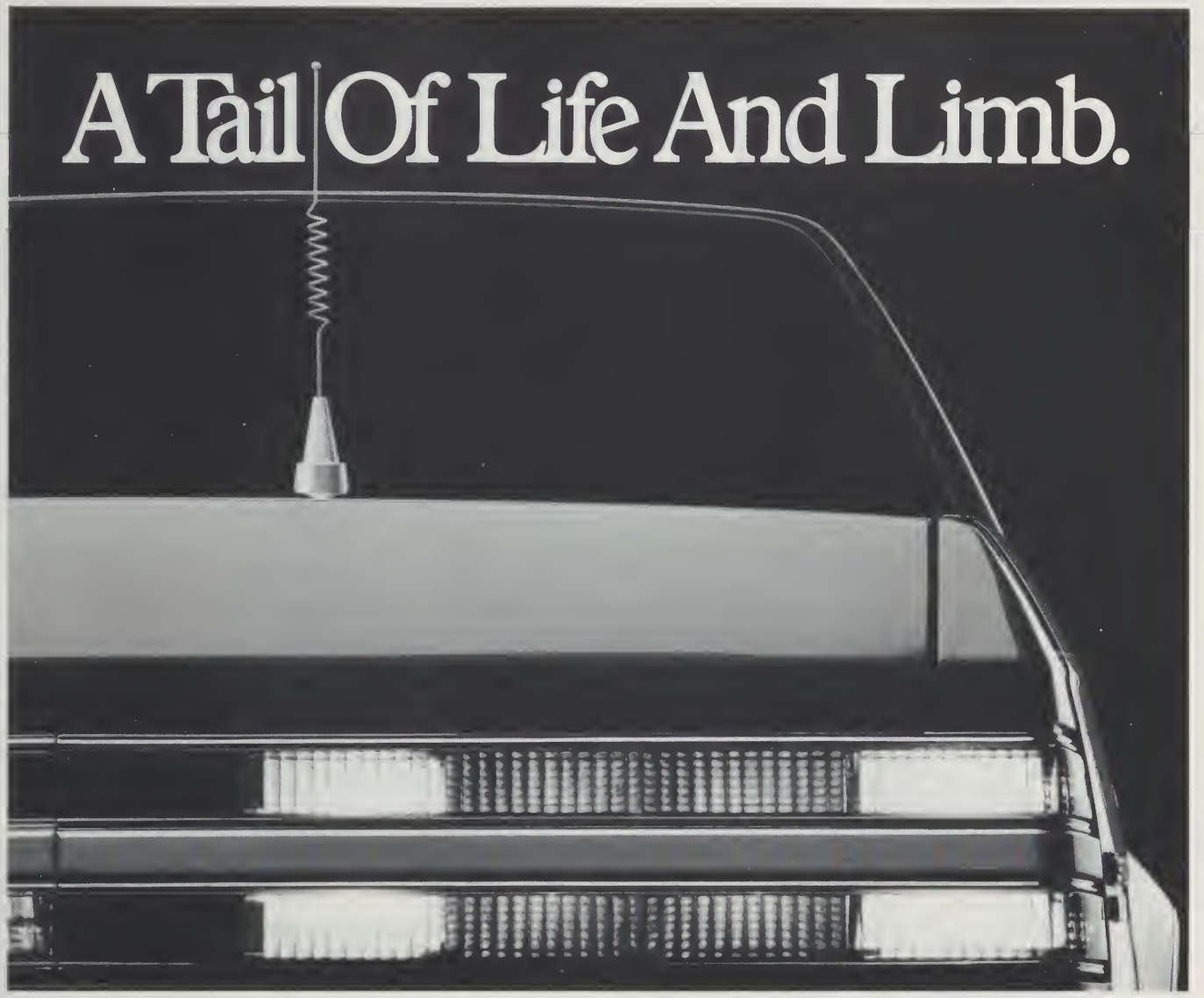
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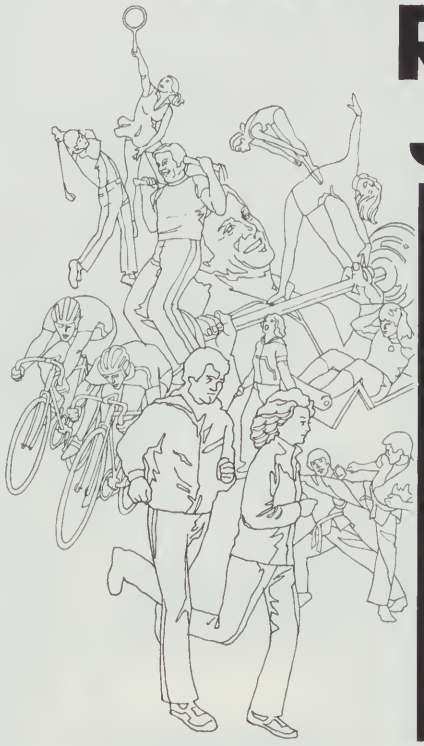
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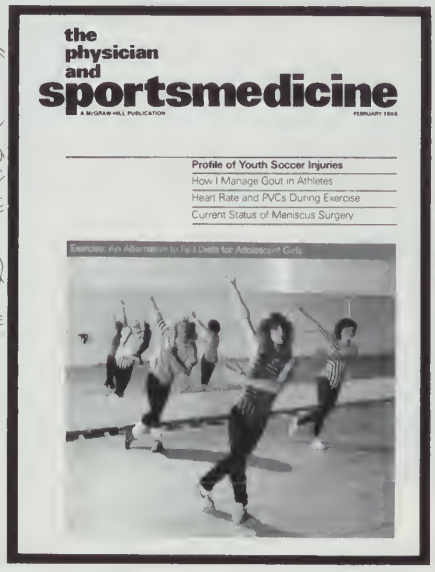
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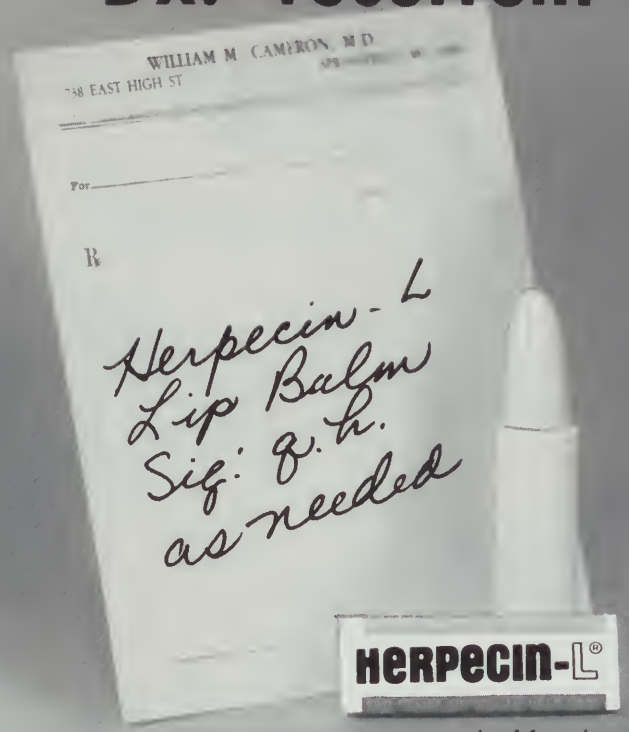
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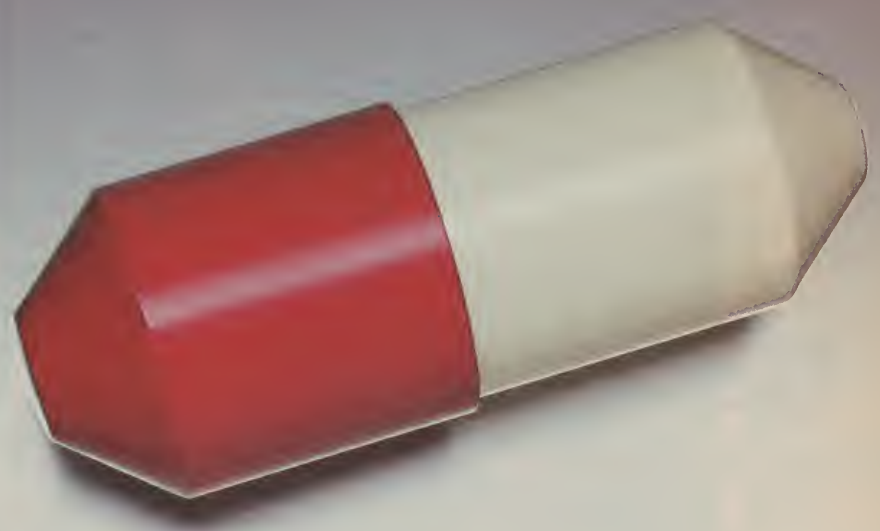
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Thiazides may add to or potentiate the action of other antihypertensive drugs.

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Contraindications: Severe left ventricular dysfunction (see *Warnings),* hypotension (systolic pressure < 90 mm Hg) or cardiogenic shock, sick sinus syndrome (except in patients with a functioning artificial ventricular pacemaker), 2nd- or 3rd-degree AV block. **Warnings:** ISOPTIN should be avoided in patients with severe left ventricular dysfunction (e.g., ejection fraction < 30% or moderate to severe symptoms of cardiac failure) and in patients with any degree of ventricular dysfunction if they are receiving a beta blocker. (See *Precautions.)* Patients with milder ventricular dysfunction should, if possible, be controlled with optimum doses of digitalis and/or diuretics before ISOPTIN is used. (Note interactions with digoxin under *Precautions.*) ISOPTIN may occasionally produce hypotension (usually asymptomatic, orthostatic, mild and controlled by decrease in ISOPTIN dose). Elevations of transaminases with and without concomitant elevations in alkaline phosphatase and bilirubin have been reported. Such elevations may disappear even with continued treatment; however, four cases of hepatocellular injury by verapamil have been proven by rechallenge. Periodic monitoring of liver function is prudent during verapamil therapy. Patients with atrial flutter or fibrillation and an accessory AV pathway (e.g. W-P-W or L-G-L syndromes) may develop increased antegrade conduction across the aberrant pathway bypassing the AV node, producing a very rapid ventricular response after receiving ISOPTIN (or digitalis). Treatment is usually D.C.-cardioversion, which has been used safely and effectively after ISOPTIN. Because of verapamil's effect on AV conduction and the SA node, 1° AV block and transient bradycardia may occur. High grade block, however, has been infrequently observed. Marked 1° or progressive 2° or 3° AV block requires a dosage reduction or, rarely, discontinuation and institution of appropriate therapy depending upon the clinical situation. Patients with hypertrophic cardiomyopathy (IHSS) received verapamil in doses up to 720 mg/day. It must be appreciated that this group of patients had a serious disease with a high mortality rate and that most were refractory or intolerant to propranolol. A variety of serious adverse effects were seen in this group of patients including sinus bradycardia, 2° AV block, sinus arrest, pulmonary edema and/or severe hypotension. Most adverse effects responded well to dose reduction and only rarely was verapamil discontinued. **Precautions:** ISOPTIN should be given cautiously to patients with impaired hepatic function (in severe dysfunction use about 30% of the normal dose) or impaired renal function, and patients should be monitored for abnormal prolongation of the PR interval or other signs of excessive pharmacologic effects. Studies in a small number of patients suggest that concomitant use of ISOPTIN and beta blockers may be beneficial in patients with chronic stable angina. Combined therapy can also have adverse effects on cardiac function. Therefore, until further studies are completed, ISOPTIN should be used alone, if possible. If combined therapy is used, close surveillance of vital signs and clinical status should be carried out. Combined therapy with ISOPTIN and propranolol should usually be avoided in patients with AV conduction abnormalities and/or depressed left ventricular function. Chronic ISOPTIN treatment increases serum digoxin levels by 50% to 70% during the first week of therapy, which can result in digitalis toxicity. The digoxin dose should be reduced when ISOPTIN is given, and the patients should be carefully monitored to avoid over- or under-digitalization. ISOPTIN may have an additive effect on lowering blood pressure in patients receiving oral antihypertensive agents. Disopyramide should not be given within 48 hours before or 24 hours after ISOPTIN administration. Until further data are obtained, combined ISOPTIN and quinidine therapy in patients with hypertrophic cardiomyopathy should probably be avoided, since significant hypotension may result. Clinical experience with the concomitant use of ISOPTIN and short- and long-acting nitrates suggest beneficial interaction without undesirable drug interactions. Adequate animal carcinogenicity studies have not been performed. One study in rats did not suggest a tumorigenic potential, and verapamil was not mutagenic in the Ames test. *Pregnancy Category C:* There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy, labor and delivery only if clearly needed. It is not known whether verapamil is excreted in breast milk; therefore, nursing should be discontinued during ISOPTIN use. **Adverse Reactions:** Hypotension (2.9%), peripheral edema (1.7%), AV block: 3rd degree (0.8%), bradycardia: HR < 50/min (1.1%), CHF or pulmonary edema (0.9%), dizziness (3.6%), headache (1.8%), fatigue (1.1%), constipation (6.3%), nausea (1.6%), elevations of liver enzymes have been reported. (See *Warnings.*) The following reactions, reported in less than 0.5%, occurred under circumstances where a causal relationship is not certain: ecchymosis, bruising, gynecomastia, psychotic symptoms, confusion, paresthesia, insomnia, somnolence, equilibrium disorder, blurred vision, syncope, muscle cramp, shakiness, claudication, hair loss, macules, spotty menstruation. **How Supplied:** ISOPTIN (verapamil HCl) is supplied in round, scored, film-coated tablets containing either 80 mg or 120 mg of verapamil hydrochloride and embossed with "ISOPTIN 80" or "ISOPTIN 120" on one side and with "KNOLL" on the reverse side. Revised August, 1984. 2385

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Healthy Mothers/Healthy Babies

The Center for Health Education, Inc. (CHE) presents this issue of the *Maryland Medical Journal*, Healthy Mothers/Healthy Babies, in cooperation with the March of Dimes Birth Defects Foundation. This issue provides the latest information on one of the principal risk factor areas associated with birth defects and birth complications—notably risks associated with individual behavior such as smoking, alcohol and substance abuse, and poor nutritional status. This information is designed to improve understanding of the relationship between these risk factors and pregnancy outcome, and the articles offer practical suggestions for physicians to positively influence patients' behaviors.

While these articles are relevant for obstetricians and gynecologists, they also have application to other primary care physicians. The guest editors recognize that the most effective health education and preventive care strategy is to reduce specific risks before conception. In this respect, primary care physicians are in an ideal position to influence behavioral change.

Evidence indicates that the recent decline in infant mortality can be attributed largely to improved survival of low birth weight infants, resulting primarily from specialized hospital-based management through neonatal intensive care programs. Sustaining the decline in infant mortality will require less costly, major new preventive actions. Physicians have been in the forefront of influencing the decline in infant mortality and now can close the treatment-prevention gap by focusing on behavioral risks and pregnancy outcome.

The article by Beverly S. Raff PhD of the March of Dimes Birth Defects Foundation introduces the theme by stating "more clearly than ever before the manner in which women of childbearing age, and pregnant women, in particular, choose to live and behave can have important consequences for the health of their offspring." While primary responsibility for behavior modification remains with the patient, physicians should be encouraged to expand their patient education role within their medical practice.

Marlyn D. Boyd PhD summarizes the data on patient motivation as an important component of pregnancy outcome. Not all women have the same level of motivation to modify their behaviors during pregnancy, and women's motivational levels change throughout pregnancy. Physicians must be aware of this and can help by serving as a patient motivator. The outcomes of the physician's efforts can be a healthier mother and child.

The next three articles review the research linking a variety of behavioral risk factors to an adverse pregnancy outcome. Paul R. Feldman MD provides compelling evidence that cigarette smoking in pregnancy has been shown to adversely affect the outcome of pregnancy for the mother, the fetus, and the developing child and addresses how physicians can influence their patients to quit smoking. Carol L. Mullins MD and Preston M. Gazaway, III, MD review the prenatal effects of alcohol and drug use in pregnancy and provide a case for management. Influencing pregnancy outcome through nutrition and dietary changes is the subject of the article by Diane L. Dimperio RD and Charles S. Mahan MD. This article highlights the finding that good nutrition is one of the most important elements contributing to the development of healthy babies and discusses steps the physician can take to help ensure an optimum pregnancy outcome.

The article by Carmine M. Valente PhD *et al.* summarizes results from a statewide survey describing the beliefs, attitudes, and self-reported practices of obstetricians and gynecologists in Maryland regarding a variety of behavioral risk factors. Findings show that while physicians believe they are prepared to counsel patients, they desire additional assistance to help patients modify their health behaviors.

David A. Nagey MD and Annelies Zachary MD, in their article on Preterm Delivery and Patient Education, state that "it is likely that the next significant decline in perinatal mortality will not be the result of new perinatal care technology but the prevention of preterm labor."

Beverly S. Raff PhD presents a brief listing of resources available to physicians through the March of Dimes.

We thank the authors for their contributions and the March of Dimes Birth Defects Foundation for their interest and support in the planning and preparation of this special issue. We also thank the Obstetrical and Gynecological Society of Maryland for their support and the Healthy Mothers/Healthy Babies Coalition for use of their logo.

ALBERT M. ANTLITZ MD
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Philosophy

HEALTH EDUCATION is a multidimensional process that informs, enables, encourages, and helps people adopt healthful lifestyles and adhere to medical advice.

Physicians are the single most credible source of health information for most people. Patients turn to their physicians for guidance and use their advice on health care matters to form the basis of their own and their family's well being. Physicians, therefore, are in a unique position to promote and bring about changes in lifestyles and habits.

However, traditional medical education has not emphasized the skills that would assist physicians in informing, encouraging and enabling their patients to modify their unhealthy behaviors and adhere to medical advice.

Health education can enhance the relationship between physician and patient. It allows the patient to make better use of health care services and increases satisfaction in the patient-physician encounter.

Purpose

The purposes of CHE are to:

- Assess and explore the role of the physician and organized medicine in health education activities.
- Implement programs for physicians that will help increase patients' adherence to medical advice.
- Develop training sessions for physicians in the techniques of promoting wellness among their patients.
- Offer opportunities for physicians to improve their communication skills.
- Work with other institutions and organizations interested and involved in health education.
- Encourage physicians and organized medicine to actively promote healthy lifestyles and a healthful environment.
- Serve as a resource for information regarding health education activities for physicians.

Accreditation

CHE has been found to meet the Essentials of Accreditation necessary to grant Continuing Medical Education credits under Category I of the American Medical Association's Physician Recognition Award.

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Dear Colleague:

The Obstetrical and Gynecological Society of Maryland is pleased to participate in this issue of the Maryland Medical Journal on improving pregnancy outcome through education. The Society acknowledges the contribution of the Center for Health Education, Inc. in heightening physician awareness by focusing on behavioral risks and pregnancy outcome. This is timely because sustaining the decline in infant mortality will require substantial new efforts directed at prevention of prematurity.

OB/GYNs participated in the dramatic decline in maternal mortality associated with modern blood banking and antimicrobial techniques and in a similar decline in perinatal mortality associated with the development of intensive care nurseries. We now have the opportunity to participate in the reduction in low birth weight infants and asphyxiated infants through the prevention of prematurity.

Physicians can and must play an important role in reducing behavioral risks by counseling women of childbearing age regarding proper nutrition and the development of behaviors that will promote the health of both mother and child. Physicians probably can have the greatest impact in the office by focusing on the following risk factors associated with pregnancy outcome:

- tobacco smoking
- alcohol consumption
- abnormal initial weight or abnormal weight gain
- preterm labor and preterm deliveries

Many organizations have developed educational programs in several different media to encourage patients to discontinue alcohol and tobacco use and to improve nutrition. There now are teaching tools for educating patients about the importance of the early detection of preterm labor. The Obstetrical and Gynecological Society of Maryland encourages its members and all obstetric health care providers to educate their patients toward improving the outcome of pregnancy.

The Society welcomes the opportunity to work with the Center for Health Education, Inc. on further educational efforts to motivate patients to change and to assist both patients and families in developing and maintaining healthier ways of living.

CLIFFORD R. WHEELESS MD
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"Life-style" Factors and Pregnancy Outcome

BEVERLY S. RAFF PhD

Raff is Vice-President for Professional Education, March of Dimes Birth Defects Foundation.

"Life-style" in the 1960s became a word associated with revolt and counterculture, embracing an anti-establishment "alternative" way of living. From the seeds of alternative living there eventually grew a concept of healthier living. Today, life-style transcends trendiness; Americans are increasingly aware of the effects of behaviors on health. In fact, people from all walks of life are coming to regard being healthy as a way of living.

As applied to the outcome of pregnancy, life-style has taken on an increased and special significance. We recognize that the manner in which women of childbearing age, and pregnant women in particular, choose to live and behave can have important consequences for the health of their offspring. Women who smoke during pregnancy have an increased risk of having a low birth weight baby. The link between alcohol consumption and fetal alcohol syndrome seems established. The effects of inadequate nutrition on pregnancy are less understood but also may contribute to low birth weight. Above all, failure to seek early prenatal care is a major risk factor.

As we document the behavioral risks associated with pregnancy, it is clear that risk reduction (that is, prevention) will be accomplished in part through behavior changes. Such changes are a result of education of the most fundamental sort: people must be motivated to assume responsibility for their health and, consequently, for the risks associated with their ways of living.

Medical professionals and voluntary health agencies such as the March of Dimes Birth Defects Foundation are committed to improving public health but must embrace the concept of education for prevention in order to be effective guardians of health. The March of Dimes commits millions of dollars annually to education programs designed to foster a general concept of good health among people of all ages. Prevention of birth defects, like prevention of other diseases and disorders, will be achieved in part through this larger concept of good health and healthy living.

The primary practitioner has an important role in disseminating information that will help patients to adopt healthy life-styles. This point was made in the *Journal* two years ago:

> We need the guidance and leadership of the medical profession to make preventive health care and health education a reality. As physicians are the first and often only contact an individual may have with the health care system, the physician's office is an ideal setting to teach people how they can protect their own well-being.[1]

It is obvious that physicians cannot carry the whole burden of attempting to influence behavioral changes. Many high-risk patients are never seen by a physician until the pregnant woman arrives at the hospital in labor. The March of Dimes recognizes it has a role to play in reaching and educating these women, and we fulfill that role through public education efforts. Physicians also should adopt the role of patient educator within their medical practices.

The responsibility for positive behavioral change remains with the patient. The mother-to-be has the responsibility to adopt a healthy life-style. Nevertheless, physicians and other health professionals can contribute to such changes by:

- Knowing the effects of behaviors that can be harmful to the mother and child
- Evaluating the problems posed by these habits
- Informing the patient of the facts and consequences, and encouraging changes to contribute to a positive pregnancy outcome

To assist the primary practitioner with informational and educational aids, the March of Dimes provides a variety of resources including literature, audiovisuals, conferences, and grants for special educational programs. Through the Maternal Nutrition Program, the March of Dimes has awarded 60 internships annually to physicians, nurses, and nutritionists engaged in maternity care. These grantees travel to the University of North Carolina School of Public Health at Chapel Hill for a two-week course of study. They learn to assess nutritional needs of pregnant women and to motivate women to improve their eating habits.

The March of Dimes provides state-of-the-art information to health practitioners through continuing education conferences. Jointly sponsored professional education conferences currently are conducted with the American Association of Family Physicians, the Nurses Association of the American College of Obstetricians and Gynecologists, and the American Dietetic Association. Through these conferences, the March of Dimes fosters collaboration and cooperation with groups of health professionals of similar interests to assure optimal care of mothers and babies.

Public health education programs carried out by the 300 chapters of March of Dimes complement the information patients receive in clinics and physicians' offices. Indeed, the chief goal of some of these programs is to get women into the office or clinic in the first place. A major national effort is the "Healthy Mothers, Healthy Babies" coalition of federal, state, professional, and voluntary health agencies. This united education campaign uses press, radio, and television to inform women about what they can do for their health and that of their unborn and newborn children.

"Good Health is Good Business," a program addressing an increasingly important life-style factor, is designed to reach men and women in the workplace with health information, particularly regarding pregnancy and childbearing. There is a growing need to reach this sector of the work force with sound health information: more than 30 percent of all births in 1983 were to working women.

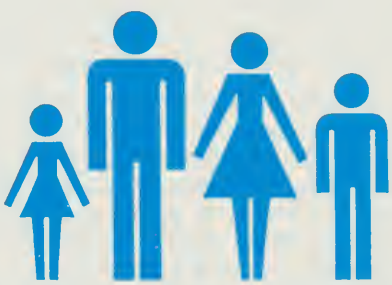
We are living in a health-conscious age. Jogging, running, aerobics, and membership in health clubs are indications of a new preoccupation with healthy living. At the same time more information about health and healthy behavior is being made available. Our experience is that many people, particularly motivated pregnant women, do care about threats posed by their behavior. When women fully understand and appreciate the risks posed to themselves and their unborn babies, they will recognize the need to change.

This is an ideal time to harness the increasing availability of health information to the motivational power and drive behind the current health-centered life-style. Certainly physicians and other health care professionals and voluntary health care organizations can join forces in promoting a concept of total good health.

Reference

1. Antlitz, A.M. and Valente, C.M. "Physician Involvement in Health Education." *Md State Med J* 32(1983):257–58.

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Patient Motivation During Pregnancy

MARLYN D. BOYD PhD

Boyd is affiliated with the Center for Health Education, Inc.

Pregnancy is a time of both physical and psychological change for women. In addition, many women find that they are expected to alter their behaviors. Motivating patients and promoting necessary changes are particular challenges for physicians.

Not all women are equally motivated to seek prenatal care early in pregnancy and to follow health care recommendations. Social, cultural, and economic factors play important roles. Some general characteristics of the motivated patient have been described. Middle-class women with better than a high school education, who are married or partnered, and who planned their pregnancy are more positive about the impending birth and more likely to become actively involved in the pregnancy and childbirth experience. Such involvement includes reading books, asking questions, and attending childbirth classes.[1-3] Women in their mid to late twenties are more likely to seek prenatal care during the first trimester.[4] Primiparas are more likely to prepare for childbirth than multiparas and are more prone to use physicians, literature, and relatives as sources of information.[5]

In addition to socioeconomic factors, the stages of a woman's pregnancy can affect her motivation. During the first months of pregnancy the mother becomes increasingly preoccupied with herself and the fetus.[6] She is receptive to information and instructions about her health and the baby's welfare. Counseling about alcohol and tobacco use, diet, and other pregnancy concerns usually is well-received. During the last trimester the mother becomes actively involved in nest-building: preparing for the baby's arrival.[6,7] This stage of pregnancy is an ideal time for the physician to discuss preparing for childbirth and for a safe environment for the baby, such as purchasing baby furniture and an approved car safety seat.

Not all women have the same motivational level, nor are they all motivated by the same concerns. The physician must be aware that motivations vary throughout a woman's pregnancy. Perhaps two of the most important changes that physicians need to motivate in a patient are their use of alcohol and tobacco.

Alcohol Use during Pregnancy

The adverse effects of maternal alcohol consumption on fetal development are well-documented. In addition to the constellation of features found in the infant who suffers from fetal alcohol effects or fetal alcohol syndrome (FAS), there are adverse maternal effects as well. Drinking mothers are at higher risk of spontaneous abortion,[8] prematurity and postmaturity,[9] premature rupture of membranes, infections, tetanic contractions, precipitate delivery,[10] and abruptio placenta.[11]

Many of the adverse maternal and fetal effects are not confined solely to alcoholic mothers. A statistically significant association has been found between alcohol use prepregnancy and during the third trimester with a decrease in birth weight.[12] The risk of FAS has been reported to increase for mothers who drank one to two drinks daily and increased markedly for mothers who drank three to four drinks a day.[13] Moreover, a relationship has been found between moderate drinking before conception and FAS[13] as well as infertility.[14]

The true prevalence of maternal drinking during pregnancy is unknown. Regional, cultural, and socioeconomic factors have a large impact on women's alcohol use.[15] Likewise, self-reports of drinking habits vary depending on the time during the pregnancy that questions are asked and the methods used to obtain the information.[14] Percentages of study populations who reported drinking sometime during pregnancy have ranged from 2 percent to 62 percent.[11,15-22]

Characteristics of drinking mothers also vary. In a Boston study[16] heavy drinkers were more likely to be older and multiparas. Few heavy drinkers were high school graduates or were employed. Heavy drinkers were more likely to be widowed, divorced, or living alone. They were more likely to smoke cigarettes and to use other drugs such as marijuana, barbiturates, psychedelics, and amphetamines. The percentage of women who reported drinking heavily was disproportionately high among white women and disproportionately low among Hispanic women. Heavy drinkers preferred beer and liquor or a combination of these. The majority of the moderate drinkers preferred beer. In another study[11] similar characteristics were identified with the addition that the heavy drinkers were more likely to have a past history of stillbirths, spontaneous abortions, and induced abortion. In contrast to these findings, a Buffalo study[14] did not find large differences in maternal drinking practices according to income, race, or urban-rural residence.

Many women in these studies reported decreasing their alcohol intake or abstaining from alcohol at some time during pregnancy. Two primary reasons were given: concern for the baby and a decreased desire for alcohol. Some women reported that alcohol did not taste good to them during pregnancy.[14,16]

The current literature available on maternal/fetal alcohol effects indicate that these negative outcomes may be prevented or markedly reduced by women avoiding or significantly reducing the amount of alcohol they consume during pregnancy.[13] Although many women feel a social expectation to stop or reduce drinking, some women still hold the mistaken notion that alcohol

use during pregnancy has some beneficial effects.[23] Moreover, many women do not obtain their information about alcohol use from highly credible sources. British studies found that only 2 percent of their subjects received information about alcohol use from health professionals.[23] In a similar study, 43 percent of the women interviewed said they did not receive any information concerning alcohol consumption during their pregnancy. Of those who did receive information, 35 percent were encouraged to quit, 64 percent were told to drink in moderation, and one woman reported that she was told it was beneficial to drink. The women listed nurses and physicians as their most common sources of information.[24]

Physicians are in an ideal position to influence women's drinking behavior during pregnancy. Because pregnant women are seen frequently over a period of several months, instruction, support, and reinforcement regarding abstinence from alcohol can be a continuous aspect of their care. Physician involvement in patient counseling about alcohol use can have positive outcomes. For example, a study[25] found that women welcomed physician counseling and that physicians could motivate those who drank heavily to abstain from drinking during their last two trimesters. Those children born to the counseled women had almost normal growth and fewer malformations as compared to the children born to women who continued to drink heavily throughout their pregnancy.

Tobacco Use during Pregnancy

Tobacco use during pregnancy has been associated with increased maternal and fetal risks including intrauterine fetal growth retardation,[26–28] spontaneous abortion,[19,29] placenta previa, abruptio placenta, and premature rupture of the membranes.[30] There also seems to be a dose/response relationship between the incidence of adverse outcomes and the amount of smoking during pregnancy.[31] Moreover, quitting or reducing tobacco use during pregnancy may decrease adverse effects. A British study[30] found that women who quit smoking before the fourth month of pregnancy had the same pregnancy outcome risks as nonsmokers. Likewise, in a Canadian study[32] perinatal mortality was reported as 27 percent higher in infants of smoking mothers. The risk increased to 35 percent if the mother smoked more than one pack a day.

The prevalence of tobacco use during pregnancy varies. McIntosh[30] reviewed studies reporting the smoking behavior of pregnant women and found the range to be between 14 percent and 61 percent. Racial differences were evident: American Orientals had the lowest percentage (14 percent); Caucasian women had the highest (61 percent). Of a total of 260,000 women, approximately 42 percent smoked while they were pregnant.

Studies have found that some women will reduce or quit smoking during pregnancy. Reasons given for stopping smoking included physician request, concern for maternal and fetal health, nausea, vomiting, and social pressure from family members.[23,33] Other factors shown to be effective include spouses with professional occupations, whether women knew someone whose health had been affected by smoking,[34] and social support provided by a female relative or friend.[35,36]

Although most women who smoke during pregnancy are aware that it is harmful to themselves and to the baby,[33] smoking cessation programs geared toward pregnant women are few, and success rates have not been promising.[31] For example, a hospital-based, intensive antismoking counseling program had no more effect on women's smoking behavior than did the standard medical care that included antismoking education.[37] Another antismoking program found no significant difference between the group who received specific counseling and the group that did not. However, a significant difference was evident one year later.[34] Finally, Danaher[38] used behavior modification techniques which showed promising results, in a smoking-cessation program for pregnant women. Of the eleven women who attended, three quit and the other eight reduced their smoking.

Why women continue to smoke during their pregnancy is unclear. Some women may believe the harmful effects do not reach the fetus.[30] Another reason is that some women may be less aware of their susceptibility to smoking risks.[39] Whatever the reasons, it is clear that pregnant smokers are no more likely to attend smoking cessation programs than nonpregnant smokers.[33] Many women will not seek out professional help to curtail or stop their smoking, but their physicians can serve as primary motivators for them.

Motivational Strategies

Studies have found that problem drinkers often will not seek help directly but that they will discuss their drinking with their physician.[40,41] Likewise, smokers indicate that their physician's advice would be a motivating factor in their quitting.[42]

Because it is often difficult for women to discuss their use of alcohol[14] and tobacco during pregnancy, the physician must use techniques that facilitate communication. Effective communication avoids confrontation, tension, and attempts by the physician to control the patient.[43,44] Studies have found that the quality of the physician-patient relationship is an important factor in patients' motivation to adhere to health care

recommendations. Patients are more motivated and likely to adhere to recommendations when the physician is perceived as friendly, concerned, sympathetic, and supportive. Patient adherence increases when the physician takes time to discuss nonmedical, social subjects, offers information freely without the patient asking for it, and when the physician gives reinforcement for the patient's progress.[45–48]

Before the physician can begin to use specific motivational strategies to help patients change their alcohol and tobacco use, an accurate assessment of the extent of the problem must be made. Studies have found that in the area of substance abuse, a self-administered questionnaire often obtains the most accurate information.[14,49] The questionnaire should be brief but elicit information about the frequency, amount, and type of alcohol or tobacco used both prepregnancy and during the pregnancy.

Questions eliciting information on what the patient believes about the use of alcohol and tobacco during pregnancy also can provide helpful information. For example, statements such as *I believe drinking when I am pregnant can harm my baby* and *I believe that if I decrease or stop smoking I will have a healthier baby* with answer options of strongly agree to strongly disagree are useful. Such questions not only provide information about the woman's alcohol and tobacco use but also provide clues as to how much knowledge she has about the effects of alcohol and tobacco use, how serious she thinks the potential problems are, and how susceptible she thinks she and her baby are to the adverse effects. Questions that assess how much the patient wants to change her behavior and how successful she thinks she will be are helpful. Success in quitting smoking has been found to vary directly with the person's motivation to change and his/her expectations for success.[50]

Other questions that can provide insight into the patient's behaviors and motivation are those assessing how much control she thinks she has over her pregnancy. If the patient does not believe she can have control over some aspects of her pregnancy she may not try to change her alcohol or tobacco use. Some women believe they can exercise a great deal of control over the outcome of their pregnancy (internal locus of control), others believe that powerful others (such as physicians, nurses, chance, or fate) control the outcome of their pregnancy (external control).[51]

Patients' beliefs about how much control they have can affect how much knowledge they have[52] and how likely they are to seek information.[51] The patient who believes she can control outcomes of her pregnancy related to alcohol and tobacco use would benefit from obtaining information, counseling, and support from the physician. If the patient believes that powerful others control the outcome then she would benefit from the physician and other health care professionals encouragement for her to take a more active role in changing her drinking and smoking behaviors. Finally, should the woman believe that chance or fate determines the outcome of her pregnancy, she would benefit from structured programs offered early in the pregnancy that would provide information, encourage questioning, and encourage the mother to be actively involved in planning strategies to change her alcohol and tobacco use.

Individual Plan

Once a complete assessment has been made, the physician can, in collaboration with the patient, develop a plan to help her decrease or stop drinking and smoking. A plan likely to lead to long-term success should include simple, specific treatment strategies, continuing support and reinforcement for the patient, prevention of a dependency relationship developing between the physician and patient, and should allow the patient to feel she is responsible for the successful changes.[53]

Because adversive pharmacological agents are not treatment options for pregnant women,[8] individual counseling and behavior modification strategies can prove useful.[38] The physician and patient can choose one or more behavior modification approaches depending on the patient's preferences and the physician's clinical judgment. Behavior modification strategies include *reminders*, *contracts*, *graduated regimen implementation*, and *self-monitoring*.[54]

Reminders include phone calls, public health nurse visits, or more frequent office visits. Reminders also help the physician and staff maintain close supervision of the patient.

Contracting involves the patient formally committing to changing a behavior. A common form of a contract is the contingency contract. For example, the patient may contract to decrease her drinking by one drink a day. In return, she may ask that her husband take out the garbage on the days she is successful or that she reward herself by resting an extra hour on her successful days. A contract must be clear and all parties involved must agree to the terms.

Graduated implementation involves changing a behavior gradually. It may be difficult for some women to suddenly stop using alcohol and tobacco because they are addictive. Although abstinence may be the ultimate treatment goal, even significant reductions can result in improved maternal and fetal outcomes.[13,30,31] By using graduated regimen implementation the woman gradually decreases her use. For example, her goal during the first week may be to decrease her cigarette use

by one-half pack three days out of seven. Once she is successful she can graduate to a one-half pack a day reduction four days and week and so on. It is important that the patient start at and progress in increments of change she can be successful with. Also, close supervision and positive reinforcement for the patient's successes are important adjuncts.

Self-monitoring can be used by patients to assess their own behavior. Keeping a diary of their alcohol and tobacco use can help them become aware of the extent of their use, of what precipitates their use, and of methods that can help them decrease their use. Talking with patients about what they have learned about themselves after keeping the diary can help motivate them to change behaviors.

In addition to the behavioral strategies, continued support from the physician and the patient's husband or partner, family, and friends is important to help keep her motivated to continue to modify her use of alcohol and tobacco. Social support is an important aspect of patient adherence to recommended regimens.[23,33,35,36]

Summary

Patient motivation is an important component of successful pregnancy outcome. Not all patients have the same level of motivation to change habits that may harm themselves or their fetus, nor do women's motivational levels stay the same throughout pregnancy. The physician can serve as a motivator throughout a woman's pregnancy by establishing open communication, by maintaining close supervision, by assisting the woman to devise a simple, specific course of action to decrease her use of alcohol and tobacco, and by helping her realize she can control her smoking and drinking. The outcomes of the physician's efforts can be a healthier mother and child.

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healthy mothers, healthy babies

Smoking and Healthy Pregnancy: Now Is the Time to Quit

PAUL R. FELDMAN MD

Dr. Feldman is a practicing obstetrician/gynecologist in Montgomery County, Maryland; is a clinical instructor at Georgetown University Hospital, Washington, DC; and is affiliated with Shady Grove Adentist Hospital in Rockville, MD.

Health hazards of cigarette smoking are well known to the medical community and the population in general. What is less well appreciated is the effect cigarette smoking can have on the outcome of pregnancy, the fetus, and the developing child. Approximately 30 percent of women in the United States currently smoke. About 25 percent of those women in the child-bearing years, and 20 percent of pregnant women smoke.[1] The literature is replete with articles suggesting that women who smoke are jeopardizing the lives of their developing fetuses.[2] Risks to the baby include more than a lower birth weight, for example, increased fetal mortality, increased neonatal mortality and morbidity, and long-term ill effects on the developing child's general health, scholastic achievement, and behavior. If a woman quits smoking early in her pregnancy, an improved outcome is expected.

Information about the hazards of maternal smoking, available to physicians and other obstetrical health care providers, is not passing from the physician to the patient. When the message does reach the patient, it usually does not convince pregnant women to stop smoking. After educating patients about the potential risks from smoking, physicians should help their patients quit smoking. For example, a physician who diagnoses hypertension in pregnancy will take an appropriate history and physical examination, will be knowledgeable about potential health risks of hypertension, and will encourage the patient to follow medical advice. The physician also will be familiar with available antihypertensive medications, dietary regimens, and will prescribe a treatment plan and follow the patient on a regular basis.

Likewise, obstetricians should be knowledgeable about the hazards of smoking and pregnancy, diagnosing the smoking problem in their patients, conducting a history and physical examination, encouraging patient compliance, and knowing the methods of ending a smoking habit. Subsequently, and on a regular basis, the physician should follow the patient who smokes. Obstetricians are in an excellent position to educate, influence, and help their patients quit smoking.

Health Hazards of Maternal Smoking

Maternal smoking is associated with adverse pregnancy outcome. In May 1983, Lawrence Longo MD testified before a Senate Subcommittee on behalf of the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics to support cigarette package warnings about the ill effects of cigarette smoking on the outcome of pregnancy. He indicated that each year almost 14,000 infant deaths would be preventable if pregnant mothers would not smoke.[3]

In 1983, "Pregnancy and Infant Health," reprinted from the *Health Consequences of Smoking for Women*, cited over 160 references dealing with smoking as it pertains to the risks in pregnancy.[4] Included are an increased risk of abruptio placenta, placenta previa, premature rupture of membranes, spontaneous abortion, stillbirth, perinatal mortality, intrauterine growth retardation (IUGR), sudden infant death syndrome, childhood respiratory illnesses and hospitalizations during childhood, lower achievement in math and reading tests, behavioral problems, and shorter attention spans. Experimental evidence points to possible concerns for the offspring of pregnant smokers including the risk of fertility problems, earlier onset of menopause, spermatogenesis impairment, and a greater chance of developing cancer during their lifetime.[5]

Maternal and Fetal Risks

Placenta previa, abruptio, premature rupture of membranes The placenta and the amniotic sac are affected by cigarette smoking in pregnancy. Placental abruption (premature separation of the placenta prior to delivery) is increased by 24 to 68 percent, and placenta previa (placental attachment and covering of inner cervix) by 25 to 92 percent.[6] A higher incidence of premature rupture of membranes also is seen in smokers.[7] Abruptio placenta usually is an emergency situation due to compromise of fetal circulation often associated with emergency cesarean birth. The maternal complications of placental abruption include hemorrhage and consumption coagulopathy.

In placenta previa, the patient will experience bleeding during much of the pregnancy and be hospitalized or bedridden until either the placenta migrates away from the cervix or the baby is mature enough to be delivered by cesarean. Premature rupture of membranes can lead to premature delivery and fetal infection. It is seen more often in mothers who smoke during their pregnancy.

Numerous pathologic abnormalities of the placenta are noted in smokers. The placentas are thinner, cover a larger diameter, and have various degenerative abnormalities of the microcirculation.[8] Perhaps the larger placental diameter accounts for the higher incidence of placenta previa since the placental edge is more likely to encroach on the cervix. Alternatively, during the period of embryonic implantation into the uterus, the more favorable part of the uterus may be the area closer to the cervix with a more abundant blood supply and

oxygenation.[9] Thus, the placenta's initial growth begins close to the cervix leading to a greater likelihood of previa as the pregnancy continues and the placental diameter increases. The degenerative histopathologic changes noted in the placenta may be the cause of the higher incidence of placental abruptions seen in cigarette smokers. The problem of premature rupture of membranes in smokers may be the result of defective ground substance, decrease amniotic sac tensile strength, or a more localized irritation of the membranes by bacteria since vaginitis and discharge are seen more commonly in cigarette smokers.[10]

Spontaneous abortion An increased incidence of spontaneous abortion is seen in cigarette smokers in a dose/response relationship. The more cigarettes smoked, the greater the risk of spontaneous abortion. In a study of more than 12,000 professional women, the risk of spontaneous abortion in smokers was 1.7 times greater than in nonsmokers.[11] It is known that early spontaneous abortions are frequently genetically abnormal. However, later spontaneous abortions are frequently due to medical illnesses and more often are genetically normal. The karyotypes of abortuses of mothers who smoke are usually normal.[12,13] Therefore, the spontaneous abortions from cigarette smoking simulate the effects of a medical problem on the mother.

Perinatal mortality Perinatal mortality (the number of fetal and neonatal deaths per 1,000 live births) is increased 1.2 times in smokers over nonsmokers.[14] Fourteen percent of preterm deliveries may be the result of maternal smoking.[15] The increase in perinatal mortality in smokers is most significant between the 20th to 32nd weeks of pregnancy.[16] Perinatal mortality is greater in high risk mothers (black, very young or old, anemic, or having lower socioeconomic status or education) compared to low-risk and nonsmoking mothers. Furthermore, a direct relationship is seen between the level of maternal smoking and the risk of perinatal loss.[17] The more a woman smokes, the greater the perinatal mortality. Analysis of stillbirths shows causes of death to be associated more often with intrauterine hypoxia, maternal causes, or consequences of preterm delivery.[18]

Small for gestational age An infant born smaller than expected for gestational age may be either premature or growth retarded. Infants born to smokers are approximately 200 grams smaller than those born to nonsmokers.[19] This smaller birth weight is due to intrauterine growth retardation (IUGR). According to four different studies, the mean gestation of smokers over nonsmokers is minimally affected, but the proportion of premature births of smokers to nonsmokers is increased by 36 to 47 percent.[20] In fact, up to 14 percent of preterm births in the United States may be secondary to maternal smoking.[21] The premature infant born to a smoker has a higher perinatal mortality.

The intrauterine growth retardation seen in smokers is independent of both maternal nutrition and genetic factors.[22] The long-term effects of IUGR on the developing child are well known. The mechanism of IUGR may be due to the fetal hypoxia created by carboxyhemoglobin, the vasoconstrictive properties of nicotine that lead to underperfusion of the uteroplacental unit, or another mechanism yet to be identified from the 4,000 chemicals existing in cigarette smoke.

Sudden infant death syndrome Numerous studies have shown a greater risk of sudden infant death syndrome (SIDS) in children whose mothers smoke during pregnancy. The risk is estimated to be 2.5 times greater in smokers over nonsmokers.[23]

Respiratory illnesses in children While respiratory distress syndrome seems to be less of a problem in the smoker's baby, due to early lung maturity, children of smokers frequent the hospital more often during the first year of life. These hospitalizations are often due to respiratory problems such as bronchitis and pneumonia.[24] Whether these problems are due to exposure to maternal smoking in utero or the effects of secondary smoke at home is difficult to measure.

Long-term effects on cognitive and behavioral development The question of long-term cognitive and behavioral development in children of mothers who smoked during their pregnancies has been examined in two very large studies, conducted in Great Britain and the United States, respectively.[25–27] Differences in children of smokers and nonsmokers are noted as early as infancy. In Saxton's behavioral assessment of infants born to smoking mothers, he concluded that the study infants showed increased irritability, decreased ability for self-control, and general lack of interest. Nonsmokers' infants tended to be less irritable and better oriented.[28]

Another study followed 17,000 children up to age 16.[29] Adjusting for other social and biological factors, the researchers concluded that the physical and mental development of these children was significantly affected. "Children of mothers who had smoked 10 or more cigarettes per day after the fourth month of pregnancy obtained significantly lower average reading and mathematic test scores than other children." Even the children whose mothers smoked less than 10 cigarettes per day did not perform as well on the math and reading tests as the children of nonsmoking mothers.

As part of the British collaborative perinatal study, Naeye and Peters looked at mental development in children whose mothers smoked.[30] Excluding such variables as secondhand exposure to smoke during childhood and family childhood rearing practices, the inves-

tigators, over a 17-year period, compared the outcomes of siblings whose mothers had smoked during one pregnancy but not the other. They concluded that "the children of smokers who had smoked throughout pregnancy had slightly lower scores on spelling and reading tests, had more frequent short attention spans, and were more often hyperactive than the children of nonsmokers." In conclusion, smoking during pregnancy has been found to affect the cognitive as well as the behavioral development of the offspring.

Fertility problems Infertility is increased in women who smoke.[31] Although the mechanism for this is unknown, the effect of nicotine on the higher centers that influence ovulation is one possibility.[32] Ovum transport has been shown to be affected by nicotine.[33] Spermatogenesis, sperm morphology, and sperm motility in males also are affected by smoking.[34]

Early onset of menopause Studies confirm an earlier mean age onset of menopause in smokers over nonsmokers.[35,36] One of the chemicals in cigarette smoke may be toxic to the ovaries.[37]

Greater chance of developing cancer The polycyclic hydrocarbons in cigarette smoke are known to be carcinogenic in laboratory animals.[38] It has been suggested that cigarette smoking in pregnancy may subject the offspring to a greater risk of carcinogenesis.[39,40]

Chemical Composition of Cigarette Smoke

Cigarette smoke has been estimated to carry between 3,000 and 4,000 chemicals including nicotine, carbon monoxide, thiocyanide, ammonia, polycyclic aromatic hydrocarbons, cadmium, plutonium, resins, tars, oxide of nitrogen, and vinyl chloride.[41,42] In the pregnant woman, these chemicals enter the respiratory passages and filter into the alveoli for absorption into the blood stream where they are carried into the general circulation. By simple diffusion, facilitated diffusion, or active transport, many of these chemicals are carried across the placental barrier to the baby.

The mechanism of these chemicals on pregnancy has been studied. Nicotine is known to be a vasoconstrictor or hypertensive agent that has been implicated in causing decreased uterine blood flow and diminished placental perfusion.[43] Thiocyanide is a hypotensive agent and diminishes the cell's ability to use oxygen.[44] Cadmium (which is implicated in bronchitis and emphysema) is known to be passed in secondhand smoke and has been found in high concentrations in the placentas of mothers whose spouses smoked, even if the mothers did not smoke.[45] Diazobenzopyrene, one of the polycyclic aromatic hydrocarbons, has been shown in laboratory animals to increase the risk of cancer in the offspring if the mothers were subjected to this chemical during pregnancy.[46]

Carbon monoxide displaces and replaces oxygen carried in hemoglobin, forming carboxyhemoglobin. Hemoglobin has a higher affinity for carbon monoxide than for oxygen. Carboxyhemoglobin levels in both the mother's serum as well as in the cord bloods of newborns of smokers are elevated. As a result of the elevated carbon monoxide levels, the displacement of oxyhemoglobin and the slower release of oxygen created by these chemical reactions has been shown to be reduced by as much as 25 percent in mothers exposed to cigarette smoke.[47]

Both long- and short-term effects of cigarette smoking on the fetus have been demonstrated. Real-time ultrasound and fetal monitoring have shown immediate increased fetal breathing, movements, activity, and increased fetal heart rate after the mother smokes a cigarette.[48] The long-term effect is decreased fetal movements, as perceived by the mother, and a higher incidence of nonreactive, nonstress tests.[49] Therefore the hypoxemic effects of carbon monoxide, decreased placental perfusion of nicotine, and some histologic abnormalities of the placenta have been implicated in causing many of the maternal and fetal problems seen in and associated with cigarette smoking during pregnancy.

Helping Pregnant Women Stop Smoking

The pregnant woman usually sees her obstetrician 10 to 16 times during the pregnancy. The obstetrician is in a good position to elicit a smoking history at the first visit, to educate the patient on a consistent basis, and to monitor and reinforce progress at each visit. Studies have shown "Women are extremely cautious about self-medications and even about taking drugs prescribed by the doctor. They don't perceive cigarettes as drugs but are readily susceptible to the suggestion that cigarettes should be considered as drugs."[50] Despite these frequent doctor/patient encounters, less than 20 percent of smokers actually become nonsmokers.

The United States Public Health Service now considers smoking to be a form of drug dependence in which nicotine is the critical agent.[51] The issue of nicotine addiction is seen best when compared to other forms of addiction, such as opium use.[52] Smokers often experiment with nicotine use at an early age. Usually there are periods of stopping and later resuming its use. Peers and other social supports are strongly influential in initiating the person to maintain the habit. Hunt has shown that the rate of relapse for heroin, alcohol, and smoking is highest during the first few months after quitting.[53] Although much milder than other addictive agents, nicotine has been shown to create a sensation

of pleasure, relaxation, and sedation for the smoker.[54] Inhaled nicotine is rapidly absorbed via the lungs into the circulation and goes directly to the brain. The smoker senses the pleasure from the affects of nicotine. Nicotine can diminish stress-related anxiety, regulate mood by creating a mild state of euphoria, and improve performance on certain kinds of tasks for the smoker.

Smokers, therefore, are not only psychologically dependent on nicotine but also have a substance/chemical dependence. Cigarette smoking is a prototype of drug abuse in which nicotine is critical. To the extent that cigarette smoking is similar to other drug abuse, strategies of treatment used for drug abusers may be applied to the treatment of cigarette smoking. In nonpregnant smokers, nicotine gum has been shown to be an excellent adjuvant to stopping cigarette use when used with behavior modification and educational experiences.[55,56]

How can the pregnant smoker stop smoking? Approximately 25 percent of pregnant women are smokers. Of those who entered pregnancy as smokers, only 17 percent quit smoking and 40 percent cut down on the number of cigarettes smoked.[57] A survey of pregnant smokers taken at the end of pregnancy showed 80 percent were aware of the hazards of smoking in pregnancy.[58] Patients reported obtaining information about the hazards of smoking from the following sources: 84 percent from the media (television), 52 percent from posters and leaflets, 37 percent from husbands, 34 percent from books or magazines, 25 percent from members of the health profession including 16 percent from doctors, and 9 percent from nurses.[59]

Can physicians influence patients to stop smoking? One study reported that 16 percent of pregnant women have been informed by their physicians that smoking in pregnancy is hazardous.[60] Other studies have shown that pregnant women would be influenced to stop if counseled by their physician. "The physician was felt to be the most credible source of health information," according to a survey performed by the "Healthy Mothers, Healthy Babies" campaign of the Public Health Service.[61,62] Seventy percent of heavy smokers in the survey said they would stop if told to do so by their physician.[63] Although almost all physicians believe it is important to counsel their patients about the hazards of smoking, only a small minority are successful at influencing smoking behavior. Physicians admit their lack of success in influencing patients to not smoke and believe that they would be more successful given appropriate support. Such support would include "referral information, patient literature, risk factor questionnaires, and physician education on behavior modification."[64]

What can physicians do to help patients stop or discontinue cigarette smoking during pregnancy? The physician can use the four basic components of a smoking cessation strategy as outlined by the Center for Health Education, Inc. in the January 1985 issue of the *Maryland Medical Journal.*

1. **Documenting the patient's smoking history.** Asking the patient "Do you smoke?" is simply not enough. Document the age of smoking onset, the number of cigarettes smoked per day, previous efforts to quit, duration of successes, and family history of smoking.
2. **Setting a quit date.** This not only tells the patient of the physician's interest and concern about quitting, but also it is more goal directed and gives the patient a chance to seek additional help if needed. It also conveys to the patient the seriousness of the physician's involvement.
3. **Preparing the patient to be a nonsmoker.** Eliciting the cooperation of friends, family, and peers has been shown to encourage compliance. In addition, smoking cessation programs are offered by the American Lung Association, American Cancer Society, March of Dimes, local hospitals and other nonprofit organizations.
4. **Reinforcing the message and monitoring the patient's progress.** Behavior modification has been shown to be a more successful method of influencing behavior than simply telling a person that they are doing something wrong. Essentially, reinforcing the positive and ignoring the negative is more likely to be successful. When the patient has had any degree of success with smoke ending, or curtailment, such as cutting down to one pack a day, it is better to commend the patient for their success with positive comments, sincere concern, a smile and a simple congratulatory "that's really good," than to say "so, you're still smoking and you are only able to cut it in half . . . too bad." The patient will be more cooperative in the future, have more confidence about their ability to continue working toward cutting down further, and may feel more assured of the physician's concern for their well-being.

Conclusion

A woman who quits smoking before conception may expect an improved pregnancy outcome. If smoking cessation can be achieved by the fourth month of pregnancy, the risks for mother and fetus are nearly as low as for the nonsmoker. Cutting down on the number of cigarettes smoked has been shown to lessen the incidence of spontaneous abortions, placenta previa, placental abruption, preterm rupture of membranes, pre-

mature delivery, sudden infant death syndrome, low birth weight, childhood growth delay, hyperkinesis, and impaired cognitive development.

The literature supports the conclusion that it is unsafe for women to smoke during pregnancy. Obstetricians should be knowledgeable of the health risks of smoking in pregnancy and be prepared to help the patient quit smoking. An understanding of the difficulties involved in stopping the smoking habit and the chemical dependency associated with smoking is essential. The less cigarettes smoked and the earlier in a pregnancy a woman quits, the safer will be the outcome for the mother, fetus, and child.

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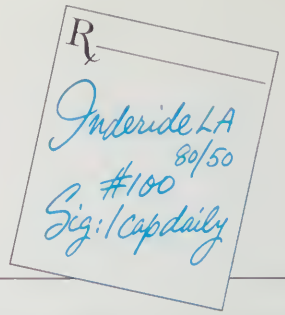
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CONTRAINDICATIONS

Propranolol hydrochloride (INDERAL®):

Propranolol is contraindicated in: 1) cardiogenic shock, 2) sinus bradycardia and greater than first degree block; 3) bronchial asthma, 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with propranolol

Hydrochlorothiazide:

Hydrochlorothiazide is contraindicated in patients with anuria or hypersensitivity to this or other sulfonamide-derived drugs

WARNINGS

Propranolol hydrochloride (INDERAL®):

CARDIAC FAILURE: Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated, and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely; or propranolol should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of propranolol therapy. Therefore, when discontinuance of propranolol is planned, the dosage should be gradually reduced and the patient carefully monitored. In addition, when propranolol is prescribed for angina pectoris, the patients should be cautioned against interruption or cessation of therapy without the physician's advice. If propranolol therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute propranolol therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

THYROTOXICOSIS: Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol does not distort thyroid function tests.

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

MAJOR SURGERY: The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

Nonallergic Bronchospasm (eg, chronic bronchitis, emphysema)—PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD, IN GENERAL, NOT RECEIVE BETA BLOCKERS. INDERAL should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

DIABETES AND HYPOGLYCEMIA: Beta-adrenergic blockade may prevent the appearance of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more difficult to adjust the dosage of insulin. Hypoglycemic attacks may be accompanied by a precipitous elevation of blood pressure.

Hydrochlorothiazide:

Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. In patients with impaired renal function, cumulative effects of the drug may develop.

Thiazides should also be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Thiazides may add to or potentiate the action of other antihypertensive drugs. Potentiation occurs with ganglionic or peripheral adrenergic-blocking drugs.

Sensitivity reactions may occur in patients with a history of allergy or bronchial asthma.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

PRECAUTIONS

Propranolol hydrochloride (INDERAL®):

GENERAL: Propranolol should be used with caution in patients with impaired hepatic or renal function. Propranolol is not indicated for the treatment of hypertensive emergencies.

Beta-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should be told that propranolol may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

CLINICAL LABORATORY TESTS: Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS: Patients receiving catecholamine-depleting drugs, such as reserpine, should be closely observed if propranolol is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity, which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies, in both rats and mice employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

PREGNANCY: Pregnancy Category C. Propranolol has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximal recommended human dose. There are no adequate and well-controlled studies in pregnant women. Propranolol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS: Propranolol is excreted in human milk. Caution should be exercised when propranolol is administered to a nursing mother.

PEDIATRIC USE: Safety and effectiveness in children have not been established.

Hydrochlorothiazide:

GENERAL: Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals.

All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance, namely: Hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Medication such as digitalis may also influence serum electrolytes. Warning signs, irrespective of cause are: Dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.

Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present or during concomitant use of corticosteroids or ACTH.

Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia can sensitize or exaggerate the response of the heart to the toxic effect of digitalis (eg, increased ventricular irritability). Hypokalemia may be avoided or treated by use of potassium supplements, such as foods with a high potassium content.

Any chloride deficit is generally mild and usually does not require specific treatment, except under extraordinary circumstances (as in liver or renal disease). Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt, except in rare instances when the hyponatremia is life-threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy.

Insulin requirements in diabetic patients may be increased, decreased, or unchanged. Diabetes mellitus which has been latent may become manifest during thiazide administration.

If progressive renal impairment becomes evident, consider withholding or discontinuing diuretic therapy.

Thiazides may decrease serum PBI levels without signs of thyroid disturbance.

Calcium excretion is decreased by thiazides. Pathologic changes in the parathyroid gland with hypercalcemia and hypophosphatemia have been observed in a few patients on prolonged thiazide therapy. The common complications of hyperparathyroidism, such as renal lithiasis, bone resorption, and peptic ulceration have not been seen. Thiazides should be discontinued before carrying out tests for parathyroid function.

DRUG INTERACTIONS: Thiazide drugs may increase the responsiveness to tubocurarine.

The antihypertensive effects of thiazides may be enhanced in the postsympathectomy patient. Thiazides may decrease arterial responsiveness to norepinephrine. This diminution is not sufficient to preclude effectiveness of the pressor agent for therapeutic use.

PREGNANCY: Pregnancy Category C. Thiazides cross the placental barrier and appear in cord blood. The use of thiazides in pregnancy requires that the anticipated benefit be weighed against possible hazards to the fetus. These hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult.

NURSING MOTHERS: Thiazides appear in human milk. If use of the drug is deemed essential, the patient should stop nursing.

PEDIATRIC USE: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Propranolol hydrochloride (INDERAL®):

Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: Bradycardia, congestive heart failure, intensification of AV block, hypotension, paresthesia of hands, thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud type.

Central Nervous System: Lightheadedness, mental depression manifested by insomnia, lassitude, weakness, fatigue, reversible mental depression progressing to catatonia, visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Gastrointestinal: Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: Pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory: Bronchospasm.

Hematologic: Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-Immune: In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: Alopecia, LE-like reactions, psoriasiform rashes; dry eyes; male impotence, and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes, and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

Hydrochlorothiazide:

Gastrointestinal: Anorexia, gastric irritation, nausea, vomiting, cramping, diarrhea, constipation; jaundice (intrahepatic cholestatic jaundice); pancreatitis; sialadenitis.

Central Nervous System: Dizziness, vertigo; paresthesias; headache, xanthopsia.

Hematologic: Leukopenia, agranulocytosis; thrombocytopenia, aplastic anemia.

Cardiovascular: Orthostatic hypotension (may be aggravated by alcohol, barbiturates, or narcotics).

Hypersensitivity: Purpura; photosensitivity; rash; urticaria; necrotizing angiitis (vasculitis, cutaneous vasculitis); fever, respiratory distress, including pneumonitis, anaphylactic reactions.

Other: Hyperglycemia, glycosuria, hyperuricemia, muscle spasm, weakness, restlessness, transient blurred vision.

Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy withdrawn.

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Alcohol and Drug Use in Pregnancy: A Case for Management

CAROL LYNN MULLINS MD and PRESTON MANN GAZAWAY, III, MD

Drs. Mullins and Gazaway are on staff, Department of Obstetrics and Gynecology, University of Maryland Hospital, Baltimore.

The United States is a drug-taking society. We are constantly bombarded by the media with advertisements for medications to cure our minor ailments. Recent attempts have altered this attitude in pregnant women, and many now consult their physicians prior to ingesting any medication. In several surveys (described by Hill) published between 1967 and 1982 the mean number of drugs used by pregnant women ranged between 3 to 5.4. The most commonly used drugs were alcohol, iron, and tobacco.[1]

Despite sporadic reports and opinions to the contrary most birth defects were attributed to genetic causes. The majority believed the fetus was impervious to the effects of noxious agents to which the mother was exposed. Not until the 1960s was this belief dispelled by the discovery of thalidomide-induced birth defects and the effects of methylmercury at Minimata Bay, Japan.[2] The pendulum now has swung in the opposite direction, and in the 1980s every drug is viewed as having potentially negative effects on the embryo and fetus.

The majority of attention has been directed toward embryonic and fetal effects of environmental agents; however, preconceptual effects have been postulated. The long premeiotic interval in spermatogenesis and meiotic interval in oogenesis provide time for environmental agents to act on the forming gametes. For example, cigarettes, caffeine, and anesthetic gas exposure in the male have been implicated in reproductive loss and low birth weight.[1] Several hypotheses have been advanced to explain these results: (1) an indirect effect upon the normal metabolic and endocrinologic function of the male; (2) direct damage to the spermatozoa; and (3) the potential of the drug within the ejaculate to affect either the intrauterine environment or the newly fertilized ova. The resting oocyte appears to be resistant to damage from environmental agents since adverse fetal and neonatal effects have not been ascertained.[1] Nevertheless, the role of environmental agents in subfertility and infertility remains to be more clearly elucidated.

During the first week postconception, the embryo is resistant to the teratogenic effects of most agents. The destruction of the embryo is more likely than the induction of congenital malformations. During the embryonic period, weeks 2 to 8, each organ system undergoes a critical stage in its development in which it may be adversely affected causing congenital anomalies. The fetus is less likely to develop congenital malformations after exposure to noxious agents since organogenesis is complete. Some of the adverse effects of environmental agents during the fetal period are growth retardation, alteration of external genitalia, altered skeletal growth, and central nervous system defects. Every fetus is probably affected by environmental factors or maternal drug ingestion; however only 2 to 3 percent of developmental defects can be attributed to a specific drug or environmental agent.[1]

We briefly review the prenatal effects of the more commonly abused substances and provide a rationale for management.

Alcohol Use

People used to view drinking as a manly pastime confined to smoky bars and fraternity parties. However, in recent years, new female drinkers outnumbered new male drinkers by a ratio of 2 to 1. This ratio is seen also among teen drinkers. Of the 10 to 18 million alcoholics in the United States, a third are women. Soon heavy drinking by women may exceed that of men.[2]

The AMA defines alcoholism as "an illness characterized by preoccupation with alcohol and loss of control over its consumption, such as to lead usually to intoxication if drinking is begun, to chronicity by progressions, and by tendency toward relapse."[3] Alcoholism and heavy drinking are no longer considered synonomous with skid row; this is particularly true of women, who generally drink covertly because of the social stigma associated with the drunken woman. The first problem, therefore, is to identify the woman with a drinking problem.

The hallmark of the initial interview is to approach the patient in a nonthreatening, nonaccusatory manner. One should use questions such as "How do you use alcohol?" rather than "How much do you drink?" Another alternative is to incorporate the ten-question drinking history developed by Rosett (Table 1) or the

Table 1. Ten-Question Drinking History for Prenatal Use

Beer:	How many times per week? _____
	How many cans each time? _____
	Ever drink more? _____
Wine:	How many times per week? _____
	How many glasses each time? _____
	Ever drink more? _____
Liquor:	How many times per week? _____
	How many drinks each time? _____
	Ever drink more? _____

Has your drinking changed over the past year?

Source: Rosett, J.L.; Weiner, L., *et al.* "Treatment Experience with Pregnant Problem Drinkers." *JAMA* 249(1983):2029.

Michigan Alcoholism Screening Test[2] as a routine portion of the prenatal history. Once the alcohol intake has been characterized, the physician should quantify her drinking and classify her accordingly.

A single drink is defined as 12 g or 15 ml (0.5 oz) of absolute ethanol, which is equivalent to 360 ml or 12 oz of beer, 120 ml or 4 oz of wine, or 36 ml or 1.2 oz of 80 proof liquor.[4] On the average, this is the quantity of alcohol that the body can metabolize within 60 minutes. Although patients tend to be vague about drinking patterns and quantities, the physician should attempt to classify her as a heavy, moderate, or rare drinker. Heavy drinkers consume five or more drinks on one occasion with at least 45 drinks per month. Moderate drinkers are those who may drink more than once a month but less than 45 drinks per month. Finally, rare drinkers imbibe less than once a month, never having more than five drinks on one occasion.[4]

Once the physician has determined a woman is abusing alcohol, a further drug history is warranted. Heavy smoking, the abuse of aspirin, acetaminophen, and sedatives, all have a positive correlation with alcohol abuse and may further compromise the pregnancy outcome.[5,6]

Women classified as heavy drinkers compose 2 to 13 percent of pregnant women and cause the most concern. Patients in this category have the highest incidence of fetal alcohol syndrome (FAS) and other associated malformations. FAS has been estimated to occur in less than 1 to 43 percent of pregnancies complicated by alcoholism.[5-7] The fully developed syndrome is characterized by severe prenatal and neonatal growth deficiency. The affected child has dysmorphic features including short palpebral fissures, thin upper lip, hypoplastic philtrum, a flat nasal bridge as well as eye, ear, and cardiac anomalies. The IQ of these children averages 68 but ranges from 16 to 105. Generally the more dysmorphic the child the lower the IQ[8] (see Table 2).

Moderate drinkers (40 percent of pregnant women) also have increased risk of malformations suggestive of FAS but rarely have the overt syndrome. Rosett noted that 11 to 19 percent of women who were moderate drinkers had abnormalities suggestive of FAS. Although the syndrome is absent, growth retardation is the most common complication. Rare drinkers and those who abstain appear to have a negligible risk for alcohol associated malformations.

Beyond FAS, the relative risk for abruptio placentae, stillbirth, low Apgar score, prematurity, low birth weight, spontaneous abortion, and congenital anomalies all are increased[5,9] (see Table 3).

The initial evaluation of the pregnant alcohol abuser includes a physical examination. One should look for hepatomegaly, splenomegaly, spider angiomata, and skin changes. If stigmata are severe, the minimal laboratory tests should include CBC, SMA-6, STS, urine culture, liver function tests, and albumin-globulin ratio to assess nutritional status.

The patient should be followed at least bimonthly to detect signs of fetal growth retardation and to reassess alcohol intake. An early second trimester Level II ultrasound exam should be performed to rule out congenital anomalies and provide a baseline should growth retardation become clinically evident. In the second trimester, weekly pelvic exams may be commenced to

Table 2. Minimum Criteria for Diagnosing the Fetal Alcohol Syndrome, As Recommended by the Fetal Alcohol Study Group of the Research Society on Alcoholism

Area	Manifestations
Growth	Prenatal or Postnatal growth retardation or both: weight, length or head circumference, or any combination of these, less than the 10th percentile for gestational age
Central nervous system function	Signs of neurologic abnormality, developmental delay or intellectual impairment
Craniofacial appearance	Characteristic abnormalities (at least two of these): Microcephaly—head circumference less than the third percentile Microphthalmia or short palpebral fissures or both Poorly developed philtrum, thin upper lip and flattening of maxillary area

Source: Sokol, R.J. "Alcohol and Abnormal Outcomes of Pregnancy." *Can Med Assoc J* 125(1981):143.

Table 3. Alcohol Use in Pregnancy: Relative Risks

Outcome	Relative Risk Ratio
Abruptio placentae	2.8
Stillbirth	2.8
Apgar 1 < 6	1.8
Apgar 5 < 6	2.4
IUGR	2.5
Congenital anomalies	4.0

Sources: Sokol, R.J. "Alcohol and Abnormal Outcomes of Pregnancy." *Can Med Assoc J* 125(1981):143. Marbury, M.C.; Linn, S.L.; *et al.* "The Association of Alcohol Consumption with Outcome of Pregnancy." *Am J Pub Health* 73(1983):1165.

detect evidence of preterm labor. Antenatal well-being testing should be used liberally.

Abstinence is the goal of treatment in pregnant women who drink. Those whose drinking is excessive and who may be alcohol dependent require a multidisciplinary approach. The patient should be encouraged to attend Alcoholics Anonymous if appropriate. Disulfiram (Antabuse) may be a potential teratogen and has no place in the management of a pregnant drinker.[5] Benzodiazepines and other sedatives should be avoided during withdrawal to minimize teratogenic effects. The woman should also be referred to a social worker, alcoholism counselor, and others as needed to provide supportive services.

Many patients will inquire whether there is a safe level of drinking. Though alcohol probably exhibits a dose and effect curve, a safe level has not been established. The effects of binge drinking or a single episode of intoxication are unknown. Therefore, all pregnant patients should be counseled that abstinence will provide the best pregnancy outcome.

Opiates

The use of opiates by pregnant women runs the gamut from rare, recreational use of one substance to chronic heroin dependence with associated polyabuse. The influence on the developing fetus is therefore dependent on the patient's exact drug habit. It is these drugs that will interrelate with the gravida's nutritional status, social, economic, and emotional environment, and ability to seek medical care.

There is disagreement in the literature regarding the fertility of women who are addicted to opiates. It was commonly believed that drug-addicted women had decreased fertility rates with an increased incidence of amenorrhea and oligoovulation,[10,11] and decreased libido. However, studies of patients on chronic high dose methadone maintenance seem to show normal menstrual patterns in treated women[12] with one small study suggesting a threefold increase in multiple births.[13] Whether the difference is secondary to the use of methadone rather than heroin, or is secondary to the difference in "life-style" seen in addicts who start methadone maintenance is unclear.

However, pregnancies do occur, and the first step is early diagnosis. Use of the patient's history of amenorrhea may be of no help. Similarly, many common urine tests for pregnancy may give false positive results in these women, ranging from 5 to 24 percent.[14] Serum B-subunit of HCG is unaffected and is the test to use. Ultrasonography may be helpful, making the diagnosis as early as three weeks postconception.

The diagnosis of opiate addiction is based on history and physical examination. The history should ascertain the severity of the woman's addiction and how much and how often heroin is used. The patient also should be questioned concerning the use of other licit or illicit drugs. Features of the physical exam that alert the physician to drug abuse include pupillary constriction, needle marks, thrombotic veins, subcutaneous abscesses, eschars, or nodules and localized edema over superficial veins.

Medical complications are frequent with infection being the most common. Bacteremia, secondary to contaminated needle use is common as is the subsequent development of subacute bacterial endocarditis and permanent valvular heart disease. Hepatitis, types A, B, non-A, and non-B are all seen. One study found that 12 percent of heroin addicts or former addicts are chronic carriers of the hepatitis B antigen. Table 4 points out many of the medical complications encountered.[14]

Obstetric complications occur more frequently in women heroin addicts than in nonaddicts[15] (see Table 5). The high incidence of low birth weight infants includes both premature deliveries and small-for-gestational-age infants. Most disturbing is the large increase in the stillbirth and neonatal death rate. Several reports reviewed by Rementeria have documented up to a sixfold increase in the incidence of stillbirths in addicted mothers.[16] Neonatal effects secondary to maternal opiate addiction are numerous. Table 6 summarizes some observations that have been recorded.[17]

The antepartum medical management must start with the realization that the substance abuser is at high risk for both medical and obstetric complications. Methadone maintenance in pregnancy was first reported over 15 years ago and has become a mainstay of therapy. The higher morbidity and mortality in patients whose addiction pattern is unaltered makes it impera-

Table 4. Medical Complications Encountered in Pregnant Addicts

Anemia	Tetanus
Bacteremia	Tuberculosis
Cardiac disease	Urinary tract infections:
Cellulitis	Cystitis
Poor dental hygiene	Urethritis
Edema	Pyelonephritis
Hepatitis-acute and chronic	Venereal disease:
Phlebitis	Condyloma acuminatum
Pneumonia	Gonorrhea
Septicemia	Herpes
	Syphilis

Source: Finnegan, L.P.; Chappel, J.N.; Kreek, M.J.; *et al.* "Narcotic Addiction in Pregnancy." In *Drug Use In Pregnancy*, Niebyl, J.R. (ed.). Philadelphia, Lea and Febiger, 1982.

Table 5. Comparison of Obstetric Complication Rates in Heroin Addicts with Total Patient Population (1969–1973)

	Incidence in Addicts (Percent)	Overall Incidence (Percent)
Abortion	14.0	12.3
Ectopic pregnancy	2.8	1.2
Birth weight < 2500 g	24.3	4.8
Premature rupture of membranes	21.1	3.9
Toxemia	12.7	4.5
Placenta previa	1.7	0.7
Abruptio placenta	4.2	0.9
Malpresentation	9.3	3.5
Puerperal morbidity	11.9	2.9

Source: Pelosi, M.; Frattarola, M.; Apuzzio, J.; *et al.* "Pregnancy Complicated by Heroin Addiction." *Obstet Gynecol* 45(1975):512.

Table 6. Effects of Maternal Narcotic Addiction on the Neonate

Adverse Effects
- Low birth weight
- Depressed Apgar scores at birth
- Accelerated weight loss in the newborn period
- Chromosomal abnormalities
- Neuromotor abnormalities

Beneficial Effects
- Low incidence of neonatal jaundice
- Absence of hyaline membrane disease even in infants with respiratory distress

Source: Wager, G. and Keith, L. "Drug Addiction In Pregnancy." In *Gynecology and Obstetrics*, Sciarra, J.J. (ed.). Hagerstown, Harper and Row, 1981.

tive that they seek other, more appropriate treatment plans. Acute detoxification has been thought to be a dangerous option. One study measured amniotic fluid amine levels after reductions in methadone dosage and found significant increases in epinephrine and nonepinephrine levels. This was thought to be evidence of fetal distress.[18]

Slow withdrawal with the use of methadone has been used by many groups with conflicting results.[17] The success rate of this relatively short-term detoxification is usually low as there is insufficient time to deal with the many social, financial, and emotional problems faced by these patients.

The dosage of methadone needs to be individualized. Withdrawal symptoms must be controlled in order to prevent use of illicit drugs and changes to the fetus. In addition, the lowest dose possible to achieve stabilization should be used, as all opiates, including methadone, have a potential adverse fetal effect.

The ideal management of this problem uses a multidisciplinary approach including psychological support, nutritional information, guidance for financial services, nursing, and social services. The obstetrician should be well acquainted with the many medical problems encountered as well as the high-risk obstetric management so often needed.

The laboratory evaluation should include: urinalysis, CBC, STS, blood type and antibody screen, HAA, tuberculosis skin test, cervical cultures for gonorrhea and herpes (if appropriate), and urine for toxicology screens. The urine toxicology screens should be repeated routinely throughout the prenatal course to rule out continuing abuse. Cervical cultures for Chlamydia, although not routine at this point, may be considered helpful in the future as there is an increased association of this pathogen with preterm labor and premature rupture of membranes.

All infections should be treated promptly when discovered including urinary tract infections, vaginitis, cervicitis, and venereal disease. Follow-up examinations and cultures, when appropriate, must be done to prove cure. Clinical parameters of fetal growth must be followed with care. Routine ultrasonography in the second trimester is recommended both as a baseline study should clinical parameters late in gestation suggest intrauterine growth retardation as well as measuring the exact age of the fetus. If possible, a Level II exam should be performed so that gross malformations, if present, may be visualized.

Fetal well-being tests, including nonstress and stress tests, biophysical profile scoring and placental function tests, may aid in diagnosing those fetuses at risk. Of course, these evaluations are mandatory when clinical situations dictate, such as the growth-retarded fetus.

Frequent pelvic exams, beginning in the late second trimester, will be helpful in detecting early cervical changes that could signal a patient at risk for preterm labor or premature rupture of membranes.

Protocol for labor and delivery should follow standards appropriate for the woman at high risk. Signs and symptoms of withdrawal must be monitored in both mother and fetus. The drug of choice for treatment of withdrawal in labor is methadone given intramuscularly. If symptoms are severe a short-acting narcotic such as meperidine (Demerol) or alphaprodine (Nisentil) would be appropriate as methadone's onset of action is 30 to 60 minutes after administration.[17]

Analgesia and anesthesia may be employed as necessary, once withdrawal is controlled.[17] Narcotic analgesia and epidural anesthesia are recommended.

Marijuana

Marijuana use is most prevalent among 18 to 25 year olds,[19] coinciding with the period of maximum fecundity. Despite widespread use of marijuana, very little is known of its effects on the developing human embryo and fetus. Most information concerning marijuana's metabolism, excretion, and teratogenic effects have been derived from animal studies. One report demonstrated that radiolabeled Δ^9THC crossed the placenta to the fetus with highest levels of radioactivity found in fetal nervous tissue.[20]

Linn *et al.* examined 880 women who reported occasional use of marijuana while pregnant. They noted the occurrence of preterm labor and abruptio placentae increased with frequent marijuana use. This group also noted a minor, though nonsignificant, increase in the relative risk of major malformations.[19] Other studies suggest a higher frequency of neurobehavioral abnormalities such as increased startle reflex, tremors, poor self-quieting, and failure to habituate to light.[2]

Further investigation is clearly needed before a definitive risk can be assigned to marijuana use during pregnancy. Present studies do not control for concomitant drug use or adulteration of marijuana with other illicit drugs. Nevertheless, marijuana use in pregnancy should be prohibited. Though apparently innocuous except for neurobehavioral effects, the long-term sequelae are unknown. In addition, marijuana may be combined with other illicit substances whose risk is unknown or deleterious.

Cocaine

Cocaine acts both as a stimulant and euphoriant. The symptoms of abuse and intoxication are characterized by hyperactivity, garrulousness, tachycardia, and hypertension. In severe cases, the abuser may become paranoid and subject to hallucinations. Cardiac arrythmias also may be present. Since cocaine is a potent vasoconstrictor, atrophic rhinitis and ischemic perforation of the nasal septum may result from "snorting." Intravenous use produces local and regional ischemia predisposing to anaerobic infection.[21]

Cocaine abusers commonly use other drugs, to combat both the drug-induced hyperactivity and the depression that is an element of withdrawal. Cocaine is commonly mixed with heroin in a cocktail known as a "speedball" for the former reason.

Research concerning cocaine abuse and pregnancy is sparse, and to date no teratogenic effects have been reported. However, Acker *et al.* have reported two cases of abruptio placentae following recent prior cocaine use. In one instance the route of self-administration was intravenous, in the other instance the route was intranasal. Both cases were associated with transient hypertension.[21]

The physician faced with a pregnant patient currently using cocaine first needs to identify and measure her habit and determine the route of administration. If intravenous use is present, the physician must be alert for the sequelae described under heroin abuse. The patient must be informed of the risk of perinatal morbidity. This may provide incentive to the patient to abandon cocaine use. Finally, if she is continually using cocaine, inpatient detoxification should be considered.

Summary

The treatment of women who abuse alcohol and drugs is directed toward fetal and neonatal well-being. The first step is to identify the patient at risk. Once identified, she is encouraged to abstain from alcohol and drugs. If addiction to heroin is the problem, then substitution with methadone is advised. Nursing support, social workers, and other counseling services must be involved. When substance abuse lessens, the physician should focus on treating the medical problems caused by the habit. These patients are high risk and need close obstetric surveillance to reduce perinatal and neonatal complications. Consultation and referral to a perinatal center is often indicated.

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The obstetrician's accurate assessment of the gravida and counseling in the area of maternal nutrition factors will have a great impact on the developing fetus.

Prepregnancy Weight

Prepregnancy weight is an indicator of maternal health status and positively correlated with infant birth weight. Higher pregravid weights are associated with both larger babies and a decreased incidence of low birth weight.[1-6] This correlation is independent of height, race, age, weight gain, and smoking.[1,2,7]

Obese women have a higher incidence of perinatal mortality[1] and medical problems,[8] therefore, risk for pregnancy outcome is more appropriately assessed on the basis of weight-for-height rather than absolute weight. Mothers underweight for their height have smaller babies and an incidence of low birth weight that is twice as high as for women whose weight is within normal limits at conception.[9,10]

The current desirable female physique is slender and fat-free. Many women in their childbearing years deliberately maintain a weight less than the standard for their height through dieting, exercise, or both. Although the risk to the fetus of an underweight mother is clearly documented, preconceptual weight-for-height is rarely considered in the obstetrical assessment.

Sophisticated measurements exist for evaluating weight-for-height, but the most practical technique in an office visit is use of a weight-for-height table. Table 1 presents a suggested guideline.

Pregnancy Weight Gain

Pregnancy weight gain has a dramatic impact on the infant and is more easily influenced by the physician than is pregravid weight.[11] Pregnancy weight gain is positively correlated with infant birth weight and inversely correlated with low birth weight. In addition to birth weight, higher pregnancy weight gains promote improved postnatal growth and neurological development of the infant.[11,12] Weight gains up to at least 40 pounds continue to improve birth outcomes.[1,13,14] The correlation between weight gain and birth outcome is independent of race, pregravid weight, age, and smoking.[1,3,6,7]

Although pregravid weight and pregnancy weight gain are independent variables, their effect on the fetus is additive. The underweight woman who gains poorly during pregnancy has about a 50 percent chance of delivering a low birth weight infant.[10,14] The probability of low birth weight is reduced significantly in under- and normal-weight women by increasing pregnancy weight gain.[10,14,15]

Data suggest that weight gain recommendations should be tailored to the woman's pregravid weight and can most appropriately be stated as minimums.

The woman at standard weight at conception should gain 25 to 30 pounds. Luke's data suggest that greater than 30 pounds weight gain may be appropriate in the small woman as compensation for low body mass.[13]

The underweight woman should gain more than 30 pounds for optimum birth outcome. A convenient rule-of-thumb is to gain the amount of deficit plus 25 to 30 pounds.

Obese Women

The management of the obese pregnant woman is difficult. "Obese" refers to anyone 20 percent over standard weight and, therefore, includes women from 30 to 200 pounds overweight. Synthesis of available data indicates the following about the obese gravida: (1) she is likely to lose or gain weight poorly;[3,6,16,17] (2) birth weight of the infant is somewhat protected from poor weight gain by the mother's higher pregravid weight;[3,6] and (3) birth weight of infants born to obese women increase in response to pregnancy weight gain.[1-3,6]

Currently, the best advice encourages weight gain in

Table 1. Suggested Guidelines for Weight*-for-Height At Conception

Height†	Small Frame (lbs)	Medium Frame (lbs)	Large Frame (lbs)
4′ 10″	88	95	104
4′ 11″	91	97	106
5′ 0″	94	100	109
5′ 1″	96	103	112
5′ 2″	99	106	115
5′ 3″	102	109	119
5′ 4″	105	113	122
5′ 5″	110	117	126
5′ 6″	113	121	129
5′ 7″	116	124	133
5′ 8″	120	128	137
5′ 9″	123	131	141
5′ 10″	127	135	145

* assumes 2 pounds of clothing
† assumes shoes are off

an obese woman that is tailored to her degree of overweight. Moderately overweight women should gain 20 to 25 pounds, and severely overweight women 15 to 20 pounds.

Pattern of Weight Gain

The desired rate of weight gain varies depending on the amount the woman needs to gain. An underweight woman should start gaining weight immediately after conception (preferably *before* conception if prepregnancy counseling is available), and if possible, reach at least her standard weight by the end of the first trimester. The normal weight women need gain is only 3 to 4 pounds by this time. The weight gain thereafter should be steady and range from 2 to 5 pounds each month, depending on the total gain desired.

Occasionally a woman will have a greater-than-average weight gain (for example, a gain of 35 pounds by 7 months). If the gain is steady, the patient appears normal, and eats to appetite, she should be instructed to eat *ad libitum* and maintain weight gain in a steady pattern. Pregnant women should never be instructed to lose weight or given a calorie restricted diet. Occasionally a woman will be eating inappropriately (for example, consuming an excess of sweets). When this occurs, counseling should be directed primarily toward constructive methods of coping and substituting more nutritious choices for empty calorie foods.

Pregnancy often is accompanied by fluid shifts manifesting as edema of the extremities or face. At this point the office scale is not a reliable tool for assessment of nutritional status. The obstetrician then must rely on fundal height and visual and dietary assessment.

Anemia

Nutritional anemias are more likely to occur during pregnancy because increased hematopoiesis creates a need for greater amounts of hematinics. Prevention and treatment of anemia traditionally has emphasized the use of iron. Therapeutic doses of iron during pregnancy have improved iron status in the mother during pregnancy and up to at least 6 months postpartum.[18,19] Prenatal iron supplements have improved iron stores in infants.[20] This has encouraged use of routine liberal doses of iron in prenatal care.

There is concern that therapeutic doses of iron may have undesirable side effects.[21,22] A major nutrition-related disadvantage of high doses of iron is iron's competitive interaction with zinc. When the ratio of iron to zinc is greater than 3, absorption of zinc is significantly decreased.[23] The effect of this change is unknown. Serum zinc in pregnant women is lower in women taking large doses of iron.[24,25]

Frequently overlooked is the role of folic acid in the development of anemia. Since folic acid is required for DNA synthesis, a deficiency will inhibit hematopoiesis. Nutrition assessment surveys suggest that low folate status is more common than is iron deficiency in unsupplemented pregnant women and may be a more significant cause of anemia.[26]

To prevent nutritional anemia a pregnant woman should receive a daily supplement of 30 to 60 mg of iron and 400 to 800 micrograms of folic acid. If measurements indicate nutritional deficiencies of either nutrient, the amount may be increased accordingly.

Dietary Assessment

Dietary evaluation of the pregnant woman should include assessment of quantity and quality of food, and identification of undesirable dietary practices. The best assessment of quantity of diet is that it promotes optimum weight gain as described above. When fluid shifts make the scale unreliable, caloric intake can be calculated and should be between 2000 and 2400 calories, depending on the woman's size, age, and activity level. Caloric adequacy is of primary importance during pregnancy because it is related to infant birth weight and, in general, is an index of other nutrient intake.[12,27]

A precise assessment of dietary quality is difficult to do in a typical office visit. Some obstetricians contract services that provide a computer analysis indicating nutrient intakes of a patient's five- to seven-day diet record. The cost for these services usually is reasonable. An analysis of nutrient intake can be tabulated using various handbooks. The nutrient intake is compared to the Required Daily Allowance (RDA) (Table 2).

Table 2. Recommended Daily Dietary Allowances, Revised 1980

					Fat-Soluble Vitamins			Water-Soluble Vitamins							Minerals				
	Age (yrs)	Wt (lb)	Ht (in)	Protein (g)	Vitamin A (RE)	Vitamin D (mcg)	Vitamin E (IU)	Vitamin C (mg)	Thiamin (mg)	Ribo-flavin (mg)	Niacin (mg)	Vitamin B6 (mg)	Folacin (mcg)	Vitamin B12 (mcg)	Calcium (mg)	Phos-phorus (mg)	Magne-sium (mg)	Iron (mg)	Zinc (mg)
Females	11–14	101	62	46	800	10	8	50	1.1	1.3	15	1.8	400	3.0	1200	1200	300	18	15
	15–18	120	64	46	800	10	8	60	1.1	1.3	14	2.0	400	3.0	1200	1200	300	18	15
	19–22	120	64	44	800	7.5	8	60	1.1	1.3	14	2.0	400	3.0	800	800	300	18	15
	23–50	120	64	44	800	5	8	60	1.0	1.2	13	2.0	400	3.0	800	800	300	18	15
	51+	120	64	44	800	5	8	60	1.0	1.2	13	2.0	400	3.0	800	800	300	10	15
Pregnant				+30	+200	+5	+2	+20	+0.4	+0.3	+2	+0.6	+400	+1.0	+400	+400	+150		+5
Lactating				+20	+400	+5	+3	+40	+0.5	+0.3	+5	+0.5	+100	+1.0	+400	+400	+150		+10

The American College of Obstetricians and Gynecologists has developed a good method of dietary assessment, which is explained in the booklet *Assessment of Maternal Nutrition*. Using a score system, it rates a weekly diet based on protein, vitamins A and C, iron, and calcium.

The most common method of dietary quality assessment is comparison of a one-day recall to standard expressed as Food Groups. The patient is asked to list what she ate for the prior 24-hour period, if it was a typical day, or what she usually consumes. Food intake is compared to the recommended intake (Table 3). Pitfalls of this method are obvious, but it is quick, requires minimal effort on the part of the patient, and provides immediate information on which to base advice.

Use of a wide variety of foods helps ensure nutrition quality. Liberal use of whole grains, raw fruits and vegetables, organ meats, nuts and seeds, and dairy products will help ensure adequate nutrition. Most diets adequate in calories meet protein requirements.

Dietary Misconceptions

Women often have misconceptions about what constitutes a good diet during pregnancy. Many believe eating three meals per day is "proper" and snacking between meals is inappropriate. Women often skip meals, especially breakfast, thinking that weight control during pregnancy is desirable. The obstetrician should assess the pattern of food consumption to ascertain if the woman is deliberately restricting food intake. Obese women should be questioned especially carefully about their pattern of eating because they are more likely to self-restrict calories.

Pregnant women who eat infrequently will have difficulty ingesting adequate calories and other nutrients and are likely to experience ketonuria. Ketonuria is thought to have a negative impact on the subsequent IQ of the offspring.[28] When found in combination with poor weight gain, ketonuria is associated with an increase in perinatal mortality.[29]

Health-conscious people often limit intake of fat, cholesterol, and sodium. These limitations are not appropriate during pregnancy. The use of whole milk and eggs will help ensure caloric adequacy. Meat, especially organ meat, is an excellent source of absorbable minerals and B vitamins. Salt to-taste will provide the sodium needed for plasma volume expansion and will enhance food flavor. This should be accompanied by drinking at least eight large glasses of noncaffeine fluid each day.

Many women think they should eliminate all sugar in their diet when they are pregnant. This is unnecessarily restrictive. As long as nutrient-dense foods supply a majority of the diet, there is no need to eliminate desserts and occasional soft drinks.

A final area of dietary assessment is identification of undesirable practices such as excessive intake of caffeine or simple sugars, inadequate fluid intake and alcohol and other drug use. Results from studies on caffeine and human pregnancy are difficult to translate into specific advice because conclusions are conflicting.[30,31] There is no justification for complete elimination of caffeine from the diet, but moderation is certainly appropriate if not from a drug perspective from a nutritional one. Caffeine has an appetite suppressant effect and is found only in foods that provide empty calories.[32] Therefore, large intake of caffeinated bever-

Table 3: Four Food Groups for Pregnancy

Food Group	Daily Servings	Definition of Serving	Additional Comments
Dairy products	4	Milk —8 oz. Hard cheese —1 oz. Cottage cheese—1 + ½ cup Yogurt	Whole milk products are preferred
Protein	2–3	Meat/Poultry/Fish—2 oz. Peanut butter —4 Tbs. Beans —1 cup Nuts —½ cup Tofu —6 oz.	
Cereal products	4–5	Bread —1 slice Cereal—½ cup Pasta —½ cup Rice —½ cup	Whole grain products are preferred
Fruits + vegetables	4	½ cup	Good vitamin C source; citrus, melons, cabbage family, tomatoes, dark/leafy greens; should be taken daily. Raw foods are better sources of vitamin C because it is destroyed by heat
		½ cup	Good vitamin A source; dark green + orange vegetables; should be taken 3 times, weekly

ages is likely to decrease both the quantity and quality of the diet. Excessive intake of simple sugars can lead to a decrease in quality of the diet when ingested instead of foods with higher nutrient density.

Inadequate fluid intake has not been scientifically studied in pregnancy, but experience indicates it may be a predisposing factor in preterm birth. Women should be encouraged to adjust fluid intake so they urinate every one to two hours, and the urine is relatively clear and odorless.

Counseling

To be successful, the process of dietary *modification* must be: (1) individualized, (2) ranked, (3) practical, (4) interactive, and (5) ongoing.

The approach to each woman should be adjusted to her interest and abilities. Some women have many questions and want to spend extra time discussing nutrition. Booklets, filmstrips, reference books, and articles for these patients' use are available through the local chapter of the March of Dimes (see article on page 1008). Other patients may not be as interested, and a shorter discussion will be more appropriate.

Dietary modifications are difficult to make and therefore should proceed slowly. If several dietary or other behavioral changes are indicated, they should be ranked and the most important made before others are attempted.

It is of paramount importance that dietary advice be practical. For instance, women not in control of food purchasing and preparation in the home can be advised of prepared snack foods that could be used to improve dietary intake.

Nutrition care plans developed jointly by obstetrician and patient will be more productive for the patient and easier for the obstetrician. Some activities the patient can do that also will save time for the physician include: (1) complete questionnaires regarding dietary habits (Table 4); (2) plot the prenatal weight gain grid; (3) list a 24-hour dietary recall or maintain a three- to seven-day diet record; (4) analyze her dietary intake by any of the methods described above; and (5) suggest changes she can make to improve her own diet. Follow-up assessment and encouragement are crucial in the process of dietary modification.

Supplementation

There is no data to support the notion that all pregnant women require a broad spectrum multivitamin. The only nutrients that need to be supplemented to all pregnant women (either because dietary intakes generally fall below recommended levels or because recommended levels are too high to be met by diet alone) are vitamin B_6,[33] folic acid, iron,[34] and zinc[24] (see Table 5 for amounts).

There should be concern about overuse of vitamins A and D because they are potentially toxic *and* teratogenic.[34,35] Vitamin A is widely available in foods, and dietary intakes usually are adequate to meet the needs of pregnancy. Vitamin D is a prehormone and is required only in the diet when there is prolonged lack of exposure to sunlight. The gravida whose hands and face are exposed to the sun for an average of 15 minutes each day probably produces most of the vitamin D she needs. A quart of milk fortified with vitamin D, drunk daily, also provides 100 percent of the pregnancy re-

Table 4: Diet Assessment for Pregnant Women

1. What was your prepregnant weight? _____
2. How much weight do you think you should gain during this pregnancy? _____
3. Are there any foods you can't eat or won't eat? _____
4. Have you been craving any foods? _____ or any: clay/dirt _____ flour _____ laundry starch _____ cornstarch _____ ice _____
5. Who does the grocery shopping in your home? _____
6. Who cooks your food? _____
7. Do you have any problems buying, storing or cooking your foods? Explain. _____
8. Do you use food stamps? _____
9. Are you having problems with: chewing food _____ constipation _____ nausea or vomiting _____ indigestion or heartburn _____
10. Are you currently on a special diet? _____
11. Are you taking any (indicate amount): pain pills _____ laxatives _____ antacids _____ baking soda _____ vitamins _____ iron _____ other medicines _____
12. How often do you use or drink: coffee _____ tea _____ cola _____ other soda _____ beer _____ alcohol _____ cigarettes _____ Koolade _____ other drugs _____
13. Have you ever taken birth control pills? _____ when? _____
14. Activity level: light _____ moderate _____ high _____
15. Do you plan to breast- or bottle-feed? _____
16. Do you have any questions about nutrition and pregnancy? Yes/No _____ If yes, explain _____

Table 5. Nutrients that Should be Supplemented During Pregnancy to the Iron-sufficient Woman

Nutrient	Amount (mg)
Vitamin B_6	10
Folic acid	0.800
Iron	30 to 60
Zinc	10 to 20

quirement. Some pregnant women are extremely sensitive to vitamin D, and experts warn that as little as two to three times the daily requirement may constitute a toxic or teratogenic dose.[36] It would seem prudent to avoid the use of supplements containing vitamins A or D during pregnancy, especially during the period of embryogenesis.

Nutrition Support

The WIC (Women, Infants and Children) program is a U.S. Department of Agriculture program designed to provide nutrition support to pregnant and breast-feeding women and to children up to age five. Participants receive nutrition counseling and monthly allotments of milk, cheese, fruit juice, eggs, and iron-rich cereals. Infants who are not breast-fed receive infant formula. Eligibility is limited to pregnant women at nutritional risk based on both financial need and nutrient status. The income guidelines do not restrict the program to welfare recipients. For instance, in the State of Maryland, a family of three with an income of $15,651 per year is eligible. Pregnant women and obstetricians find the expertise of the professional WIC staff, the extra food the program provides, and the improved nutrient intake of the pregnant woman beneficial.

When an obstetrician has a patient with severe or unusual nutritional problems (who is ineligible for the WIC program), nutritionists now are available in most health departments, in private practice, or in hospital "wellness" programs. Referral to these professionals can help greatly in management of patients with difficult dietary problems.

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Behavioral Risks and Pregnancy Outcome: Attitudes and Practices of OB/GYNS

CARMINE M. VALENTE PhD; JEFFERY SOBAL PhD; HERBERT L. MUNCIE, Jr., MD; DAVID M. LEVINE MD; ALBERT M. ANTLITZ MD; and BRUCE R. DeFORGE MA

Valente is Executive Director of the Center for Health Education, Inc.; Sobal is Assistant Professor, Department of Family Medicine, University of Maryland; Dr. Muncie is Associate Professor, Department of Family Medicine, University of Maryland; Dr. Levine is Professor of Medicine, Johns Hopkins University, School of Medicine; Dr. Antlitz is a cardiologist and Chairman of the Board of Directors, Center for Health Education, Inc.; DeForge is a research analyst, Department of Family Medicine, University of Maryland.

As described in other articles of this issue, current research indicates that a variety of risk factors are associated with an adverse pregnancy outcome. The presence of risk factors in a woman suggests an increased chance of birth defects, and pregnancy and birth complications. These factors include demographic risks (for example, age, race, socioeconomic status); medical risks that can be identified before pregnancy (diabetes, hypertension); medical risks that can be identified only during pregnancy (multiple pregnancy, poor weight gain); risks associated with health care (for example, inadequate prenatal care); environmental risks; and behavioral risks.[1] In this article we define behavioral risks as smoking, alcohol and substance abuse, and poor nutritional status. All are modifiable prior to and during pregnancy.

Pregnant women need to make greater efforts to reduce their risks of incurring an adverse pregnancy outcome; physicians, especially obstetricians and gynecologists (OB/GYNs), are in a unique position to positively influence the behavior of their patients. The most effective health education and preventive care strategy is to identify and reduce specific risks before conception. Numerous opportunities exist to reduce behavioral risks before pregnancy, yet these often are overlooked in favor of interventions during pregnancy.

While physicians are cited by the public as the single best, most reliable, and credible source of health information[2,3] and while physicians can be effective agents in influencing patient attitudes and behaviors toward risk-factor reduction, there is a paucity of research describing the beliefs and practices of physicians regarding risk factors. We describe the beliefs, attitudes, and self-reported practices of obstetricians and gynecologists in Maryland in this area.

Methods

Data for this article was drawn from a sample of 1,040 primary care physicians (Family/General Practitioners, Internists, Obstetricians, and Gynecologists) who responded to a survey on health promotion.[4,5] The survey was conducted in June 1983 by the Center for Health Education, Inc. (CHE) and the Department of Family Medicine, University of Maryland School of Medicine, in cooperation with Johns Hopkins University, School of Hygiene and Public Health. The survey was mailed to 1,715 physicians in Maryland and included a 50 percent random sample from the metropolitan areas of the state and all primary care physicians in the remaining 19 counties. After three mailings, a 65 percent response rate was obtained. Data were weighted for the analysis to reflect the state's physician population. The data presented herein include the responses of obstetricians and gynecologists in the survey (weighted N = 308).

Results

Several questions about behavioral risks and the preparedness and success of obstetricians and gynecologists in modifying patients' behaviors were addressed. Obstetricians and gynecologists were asked if physicians should try to modify people's behaviors in an effort to minimize risk factors. Ninety-six percent believed they should do so.

Obstetricians and gynecologists were asked about the importance of behavioral factors in promoting health. Of the behavioral factors linked to an adverse pregnancy, obstetricians and gynecologists most frequently considered the following to be "very" or "somewhat" important actions to take to reduce risk: eliminate cigarette smoking (99 percent); avoid excess calories (98 percent); eat a balanced diet (96 percent); drink alcohol moderately (85 percent); and avoid alcohol completely (43 percent).

A majority of obstetricians and gynecologists reported that they were prepared to counsel patients in the risk-factor areas (see Table 1). More than two-thirds of the obstetricians and gynecologists (70 percent) reported they were prepared to counsel patients regarding smoking cessation, while only slightly more than half (56 percent) reported being prepared to counsel patients in nutritional areas. The complexity and changing nature of nutrition education may account for obstetricians' and gynecologists' sense that they are not as well prepared to counsel in this area.

Table 1. Percentage of OB/GYNs Expressing Preparedness in Counseling Patients

Smoking cessation	70
Alcohol use	65
Drug use	64
Nutritional areas	56

While obstetricians and gynecologists generally indicated they were prepared to counsel patients, they did not perceive themselves as being overly successful in helping patients change behavior (see Table 2). In the areas of drug and alcohol use, 19 percent more obstetricians and gynecologists reported being prepared to counsel than reported being successful in counseling. A slightly smaller difference also is noted in the nutrition and smoking cessation categories.

Physicians were asked how successful they could be (if given appropriate support) in helping patients change behaviors. Only 1.3 to 3.9 percent of obstetricians and gynecologists described themselves as being "very successful" in helping patients change their behaviors. However, if given appropriate support, an additional 12.3 to 16.9 percent reported they could be "very successful" in helping patients change behavior (see Table 3).

Physicians were also asked what type of support and/or assistance might be helpful to them in working with patients. Obstetricians and gynecologists reported that if given appropriate support, they could be several times more effective in influencing behavioral change (see Table 4). A wide variety of supports were noted by most obstetricians and gynecologists.

Table 2. Percentage of OB/GYNs Reporting Success in Modifying Behavior

	Very Successful	Successful	Total
Smoking cessation	2.9	51.6	54.5
Nutritional areas	3.9	48.7	52.6
Alcohol use	1.3	45.1	46.4
Drug use	3.6	41.9	45.5

Table 3. Percentage of OB/GYNs Reporting Being Currently versus Potentially Very Successful in Changing Patient Behaviors

	Currently Very Successful	Potentially Very Successful Given Support	Difference
Smoking cessation	2.9	19.8	16.9
Alcohol use	1.3	17.2	15.9
Drug use	3.6	17.9	14.3
Nutritional areas	3.9	16.2	12.3

Discussion

Although established behaviors such as cigarette smoking or use of alcohol and other drugs are difficult to alter, future improvement in pregnancy outcome will require changes in these behaviors. Obstetricians and gynecologists are ideally situated to have a substantial impact on the behavior of their patients. Our data demonstrate that obstetricians and gynecologists in Maryland are aware of this opportunity, strongly believe it is part of their responsibility, and also believe they are relatively prepared to help counsel patients.

Although obstetricians and gynecologists did not report they were very successful in changing patient behavior, they reported they could be several times more successful if given appropriate support. Obstetricians and gynecologists indicated the need for a wide array of support services that would be helpful to them

Table 4. Percentage of OB/GYNs Reporting Types of Support or Assistance as "Very or Somewhat" Valuable

94	Information on where to refer patients
90	Literature for distribution to patients
86	Preprinted risk factor questionnaires
82	Physician education in specific subjects such as alcohol or nutrition
81	Training for support staff
80	Videotapes for use with patients
76	Physician education in behavior modification
74	Financial reimbursement to hire additional staff
68	Financial reimbursement for time spent with patients

in working with their patients, ranging from information on where to refer patients to physician education in behavior modification to financial reimbursement for time spent with patients. The Center for Health Education, Inc. is interested in working with the obstetrical and gynecological community in Maryland to develop educational approaches that will attempt to bridge the gap between obstetricians' and gynecologists' current success and their potential success in influencing behavioral risk factors related to pregnancy outcome.

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In Appreciation

J. Emmett Queen MD served on the Board of Directors of the Center for Health Education, Inc. (CHE) from its founding in April 1982 to his retirement from Blue Cross of Maryland in January 1985. CHE thanks Dr. Queen for his interest and support in physician education.

Appointments

The Center for Health Education, Inc. (CHE) announces the appointment of Robert E. Scalettar MD, MPH and Jose M. Yosuico MD to its Board of Directors.

Preterm Delivery and Patient Education

DAVID A. NAGEY MD and ANNELIES ZACHARY MD

Dr. Nagey is Associate Professor and Director, Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, University of Maryland School of Medicine. Dr. Zachary is Chief, Office of Maternal Health, Family Planning and Hereditary Disorders; Preventive Medicine Administration; Maryland Department of Health and Mental Hygiene.

Recent studies have demonstrated it is possible to almost halve the current perinatal mortality rate by expending resources that are quite modest compared to expected savings. The most recent statistics[1] list 762 infant deaths in Maryland in 1982 (11.9 per thousand live births). This places Maryland 35th in the nation with a rate near the national average of 11.5 infant deaths per thousand live births. More people die as infants each year in America (42,401 in 1982) than die of breast cancer (37,685) or leukemia (16,704).

In the United States (and presumably Maryland) 60 to 80 percent of perinatal deaths occur in premature infants (infants and fetuses prior to 37 completed weeks of gestation) despite the fact that these account for only 7 to 8 percent[2] of all pregnancies. An intensive program of risk screening,[3] patient and staff education, and prenatal care[4] has been shown to decrease the incidence of prematurity by half or more in several programs applied to diverse populations.[4–6] Educating patients to the sometimes subtle signs and symptoms of premature labor (Table), coaching them to call or present themselves to the hospital delivery room immediately on noting these signs or symptoms, and (perhaps most importantly) emphasizing the importance of early recognition and aggressive treatment of preterm labor to delivery room nurses and physicians will result in a decrease of preterm delivery.

Virtually every patient who calls in a complaint or concern referrable to preterm labor should be asked to present herself for examination. A majority of these patients should receive a careful cervical assessment along with abdominal palpation and 30 to 60 minutes of electronic/fetal monitoring to rule out labor or contractions. Patients having contractions but not labor (that is, no change in the cervix) should be admitted for at least 3 to 5 hours of observation lest cervical change (labor) should develop. Patients in preterm labor then can be treated with tocolytic agents with a high expectation (40 to 80 percent)[7,8] that their labor can be arrested for a significant time.

Table. Symptoms of Preterm Labor

- Regular uterine contractions, with or without discomfort
- Dull low backache, pressure, or pain of recent onset
- Intermittent lower abdominal or thigh pain
- Intestinal "cramping" with or without diarrhea or indigestion
- A change in vaginal discharge

Source: Modified from Herron, M.A.: Katz, M.; and Creasy, R.K. "Evaluation of a Preterm Birth Prevention Program: Preliminary Report." *Obstet Gynecol* 59 (1982): 452–56.

Cost Concerns

A reasonable concern is that this management approach will exhaust obstetricians, obstetric nurses, and will clog delivery and emergency rooms with patients having symptoms of preterm labor. Such exhaustion may be the cost of optimal medical care. Those concerned about costs will be encouraged by the cost/benefit ratio of these admissions compared to the cost of intensive care in the nursery. Physicians concerned about their time involvement should be reassured that this intensive approach to preterm labor does not dramatically change the number of telephone calls or hospital visits. At the same time, increased awareness of the importance of preterm labor has the benefit of making the patient feel involved in prenatal care and intensifying the feeling that prenatal care is a team effort. Heightened sensitivity of the importance of recognizing preterm labor and the resultant prenatal visits and cervical examinations is a small price to pay compared to a preterm birth.

By implementing the above along with weekly cervical examinations in patients at high risk for preterm labor, as shown by a risk-scoring[3] scheme, Creasy reduced the incidence of preterm labor in his hospital from 6 to 8 percent to 2.4 percent.[4] Papiernik, in studies less well-controlled, but with a similar protocol, also was able to significantly reduce the incidence of prematurity.[6]

Gains in the perinatal/neonatal mortality rate have been hard won. While Creasy's method appears transferable, the application of his protocol requires significant patient, physician, and nurse effort. Even the less intense but broader efforts in Maryland, coordinated by the Healthy Mothers/Healthy Babies Coalition, have demanded a significant number of volunteer professional hours. These efforts include continuing medical education and public service announcements concerning the importance of early detection of preterm labor, smoking, alcohol and other substance abuse cessation efforts, early prenatal care, and good maternal nutrition. Whether this broader appeal to the public will be effective is being investigated on a limited scale. Additionally, prophylactic tocolytic agents are being studied with a randomized, double-blinded, prospective protocol at the University of Maryland School of Medicine in patients at high risk for preterm labor. Although there are a number of questions yet to be answered, there is no question that the prematurity rate can be decreased, perhaps by half, as demonstrated by Creasy

and others.

Are there other solutions? Neonatal mortality data from Colorado[9,10] show a dramatic 80 percent improvement in the neonatal mortality rate for a 1000 gram (2 lb 1 oz) infant born at 30 weeks. Moreover, the intensive care nursery solution has become very expensive. The *average* 1000 gram survivor can expect a 70-day hospital stay with an average bill of $1,500 per day.[11] The cost of such a stay at $105,000 would buy a *lot* of prevention. As others have put it so succintly: "Womb rent is cheaper than room rent."[12]

In the Maryland Healthy Mothers/Healthy Babies program, several obstetricians have voiced concern that following Creasy's protocol would result in most patients spending half their pregnancies at the hospital or on the telephone to their obstetricians. As pointed out in the Healthy Mothers/Healthy Babies program, the physician's time commitment is small, and the yield is great in terms of both improved pregnancy outcome and improved physician patient relations.

Patient Education

The process of patient education should begin with the first prenatal visit. In addition to discussing seatbelt use in pregnancy, nutrition, exercise, and coitus during pregnancy, the obstetric health care provider should state that preterm labor is a potentially serious complication of pregnancy. Throughout prenatal care, patient education should include the importance of early detection of preterm labor and the steps the patient should take if labor occurs. At this time, the patient should be urged to call with symptoms of labor, regardless of the stage of pregnancy. The distribution of patient education materials should include information on preterm labor. For patients who may have to deal with a delivery or emergency room staff not under the obstetrician's aegis, preparation is in order to ensure that the patients' concerns about preterm labor are understood.

Patient education materials on this topic and other related topics are available at little or no cost. These materials and their sources are listed in the article beginning on page 1008. Particular attention is drawn to another great killer of babies: automobile accidents. Since one of every fourteen pregnant women has an automobile accident while pregnant,[13] various seatbelt campaigns are of particular importance.

The improvement in neonatal mortality and morbidity in the last 20 years primarily has been due to advances in technology in neonatal care of the low birth weight infant and secondarily to application of new technology to obstetrics. Further advances most likely will be made by the prevention of preterm delivery. Preterm delivery can be prevented much more cheaply than prematurity can be treated. Physicians are in an ideal position to educate their patients about preterm delivery.

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Resources Available from the March of Dimes

BEVERLY S. RAFF PhD

Raff is Vice-President for Professional Education, March of Dimes Birth Defects Foundation.

The March of Dimes Birth Defects Foundation commits millions of dollars annually to education programs. Through more than 400 local chapters, the March of Dimes is a resource to physicians and other health professionals. Staff of the Departments of Professional Education and Community Services and other March of Dimes specialists are available for consultation.

Professional Education

Professional education seeks to improve and expand perinatal and genetic service by disseminating new knowledge and providing assistance in the training of health professionals. Each year the March of Dimes organizes medical and scientific conferences around the country to keep health professionals abreast of developments in perinatal research and clinical applications.

Publications and audiovisuals have been produced to assist health professionals and researchers involved with genetics, perinatal care, and birth defects. Material dealing with life-style factors can be found in a variety of our professional health education publications.

In addition to materials for physicians, the March of Dimes produces a Staff Development Program for nurses. These booklets are designed to assist nurses in providing optimal health care for perinatal clients. Patient education is emphasized in these programs. Some of the booklets that relate to life-styles and pregnancy outcome are:

Nutrition and Weight Gain During Pregnancy
Preterm Labor
Psychosocial Aspects of Childbearing

The publications in the March of Dimes, Birth Defects: Original Article Series are concerned with prenatal care and pregnancy outcome. They include:

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Provides an overview of the incidence, risks, and consequences of pregnancy and childbearing for both the adolescent and the infant.

Perinatal Parental Behavior: Nursing Research and Implications for Newborn Health

This book deals with studies of human relationships and parenthood, with implications for primary and preventive health care.

The following reprints address topics that can improve the outcome of pregnancy, prevent birth defects, or ameliorate the effects of birth defects.

The Fetal Alcohol Syndrome: Cause for Concern

The article describes the effects on the fetus of exposure to alcohol.

Nutrition Intervention in the Community—The WIC Program

Reports on the Women, Infants, and Children (WIC) program in Massachusetts, the eligibility requirements and services provided, and the improved outcome for the newborns.

Preparenting and Prenatal Care: First Steps to High Level Wellness

Discusses the need for prenatal care and offers specific guidelines that should be given to every pregnant woman.

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Teratology for the Obstetrician: Current Status

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Evaluation of a Preterm Birth Prevention Program: Preliminary Report

This reprint presents a clinical study describing the effectiveness of a preterm birth prevention program.

Herpes Genitalis and the Childbearing Cycle

This article describes the effects of this disease on pregnancy and the newborn.

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Discusses immunization against rubella and the status of efforts to prevent various other infections of the fetus and newborn.

Neonatal Mortality Risk in Relation to Birth Weight and Gestational Age: Update

Presents neonatal mortality risk for all birth weight-gestational age categories based on data from a study at the University of Colorado Health Sciences Center from 1974 to 1980.

Community Services

The March of Dimes develops and distributes educational materials to schools, youth-serving agencies, businesses, and health care facilities. These print and audiovisual materials are designed to encourage group and individual behavior patterns conducive to a positive outcome of pregnancy. Physicians may find many of these materials of special interest to them as they seek to foster positive life-styles among their patients. Many of the following materials can be distributed by physicians to patients in offices or clinics. A Catalog of Public Health Education Materials is available from your local March of Dimes Chapter. In greater Baltimore call 301-752-7990 and in the National Capital area call 301-942-5972.

These printed materials deal with life-style factors:

Family Medical Record
A simple, comprehensive form for keeping vital family health information. Self-mailer.

Family Health Tree
Family project designed to trace health histories over four generations.

Teenage Pregnancy Fact Sheet
Facts and figures about the consequences of adolescent pregnancy.

Be Good to Your Baby Before It Is Born (also in Spanish)
Booklet describes what every pregnant woman wants and needs to know to help protect her baby's and her own health.

Dad, It's Your Baby Too
Emphasizes importance of the support role of the father.

You Are Pregnant, You're in Your Teens, and You Need Help
Directs pregnant teens to resources and people that can help them. Gives information on good prenatal care.

*D*A*T*A*—Drugs, Alcohol and Tobacco Abuse During Pregnancy*
Pamphlet about the risks to an unborn baby from prescription and over-the-counter drugs, as well as alcohol and cigarettes.

Will My Drinking Hurt My Baby?
Pamphlet explaining Fetal Alcohol Syndrome and the damaging effects of excessive drinking on the unborn child.

Sexually Transmitted Diseases
Pamphlet about the symptoms, treatment, and prevention of venereal diseases.

Babies Don't Thrive in Smoke-Filled Wombs
Outlines the dangers of smoking for mothers and babies.

Genetic Counseling
This easy-to-read booklet explains the "why" and "how" of family health histories and scientific tests for inherited conditions for families referred to genetic counselors, students, and allied health workers.

For additional information on March of Dimes education programs, contact your local March of Dimes Chapter or write:

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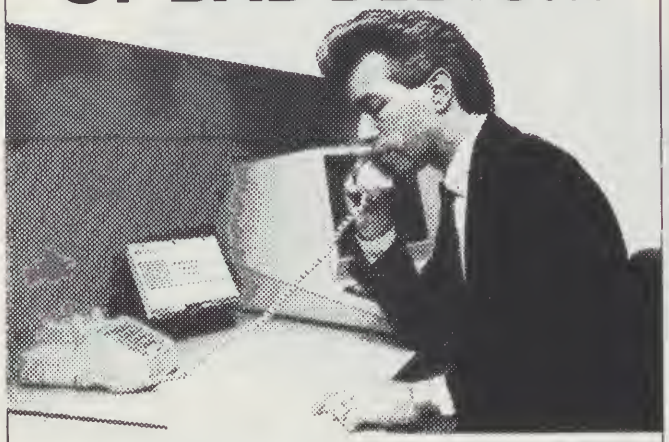
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Oct 21–25 Twenty-seventh Annual Emil Novak Memorial Course: Gynecology, Gynecological Pathology, and High-Risk Obstetrics. Fee: $550 regular, $400 residents; 47 3/4 AMA Cat I credits.

Nov 1 Diabetic Retinopathy. Fee: $150 physicians, $75 residents and fellows; 9.5 AMA Cat I credits. Info: J. Ryan 301-955-6046.

Nov 2–3 Hemodynamic Monitoring/Patient Care and Pulmonary Artery Catheterization, at the Preclinical Teaching Bldg., 725 N. Wolfe Street. Fee: $350; 12.5 AMA Cat I credits. Info: J. Ryan 301-955-6046.

Nov 6 Update in Infectious Diseases, sponsored by the Department of Infectious Diseases. Fee: $20; 4 CME Cat I credits. Info: C. Sentman 301-955-6046.

Nov 13–15 Principles and Mechanisms of Neurotoxicity, School of Hygiene and Public Health. Info: J. Corn 301-955-2609.

Nov 15 Hypertension Symposium, Hyatt Regency, Baltimore. Fee: $25; 4 CME Cat I credits. Info: C. Sentman 301-955-6046.

Nov 15 Progress in Pediatrics 1985. Fee: $80 physicians, $40 residents; 11 AMA Cat I credits. Info: J. Ryan 301-955-6046.

Nov 16 Seminar on Toxicologic Emergencies, sponsored by the Department of Emergency Medicine and Maryland Poison Control Center. Fee: $55; 6 AMA, ACEP and other appropriate credit pending.

Nov 18 Update on Acquired Immune Deficiency Syndrome (AIDS) for the Primary Care Physician, co-sponsor Department of Health and Human Services, US Public Health Service, Region III. Fee: physicians $70; other health professionals $50; appropriate credits applied for. Info: P. Macedonia 301-955-6085.

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The Department of Radiology and Radiological Science, offers several courses in abdominal and obstetrical ultrasound: courses scheduled Jan 14 to Dec 6, 1985. Info: Joan Mosmiller, Department of Radiology (301-955-8450).

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Application and completed preregistration is advised ASAP: completed preregistration must be done before March 28, 1986, unless by special arrangement. Info: John K. Frost MD, 604 Pathology Bldg, The Johns Hopkins Hospital, Baltimore, MD 21205, USA

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University of Maryland School of Medicine

CME Courses: For each course additional information may be obtained by contacting Program of Continuing Education, University of Maryland School of Medicine, Room 300, MSTF, 10 South Pine St., Baltimore, MD 21201 (301-528-3956).

Nov 13 Practical Psychopharmacologic Management of Anxiety Syndrome. International Hotel at BWI. Fee: $40; 6 AMA Cat I Credits.

Nov 21–23 Symposium on Obstetrics and Gynecology: An Up-to-Date Postgraduate Course. Baltimore Plaza Hotel. Fee: $150; 13 AMA Cat I credits.

Nov 23 Alzheimer's, Dementia and Related Disorders: Diagnosis and Medical Treatment. Hyatt Regency, Baltimore. Fee: TBA; 6 AMA Cat I credits.

Dec 6 Hypertension Symposium. UMAB Campus. Fee: TBA; 6 AMA Cat I credits.

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Miscellaneous Meetings

Oct 25–27 Health Care—Impact of Government and Corporate America, a national seminar sponsored by the American College of Utilization Review Physicians (ACURP) in Washington, DC. 10 Cat I credits from ACURP. Each day will have a specific theme: Friday, "Government's Impact on Health Care"; Saturday, "The Physician's Quest to Assure Quality Health Care"; and Sunday, "How the Cost Containment Pressures of Corporate American are Effecting Health Care." Info: ACURP, 30 N. 36th St., Camp Hill, PA 17011 (717-737-5660).

Nov 1–2 Training for Health: Prevention and Treatment of Common Athletic Injuries, Philadelphia, PA, sponsored by Trieber Assoc., Inc., and Southern Medical Assoc. Fee $350 (including hotel); info: Trieber Assoc., Inc., 9407 Jodale Rd., Randallstown, MD 21113 (301-655-5062).

Nov 5–8 Fall Meeting American Academy of Clinical Anesthesiologists, Atlantic City, New Jersey, Resorts International Hotel. Info: AACA, POB 11691, Knoxville, TN 37939 (615-588-6279).

Nov 13–14 Current Controversies in the Management of Prostate Carcinoma, presented by the American Cancer Society at the Inner Harbor Hyatt Regency, Baltimore. Info: K.T. Drake MD 301-828-2540.

Nov 14–15 Pediatric Head Injury: Innovative Approaches to Rehabilitation, presented by the Rehabilitation Institute of Pittsburgh. Info: The Rehabilitation Institute of Pittsburgh, 6301 Northumberland St., Pittsburgh, PA 15217 (412-521-9000, ext. 325 or 343).

Nov 20–22 8th National Trauma Symposium-Making a Difference, Sheraton Inner Harbor, Baltimore. Info: P. McAllister 301-528-2399.

Nov 26 Artificial Heart Implant, William DeVries MD. Maryland General Hospital's C.W. Stewart Memorial Lecture. Info: 301-225-8790.

Dec 4–6 Recent Advances in Clinical Medicine. Info: Chairman, Department of Medicine, Box 466, Charlottesville, VA 22908 (804-924-2042).

March 5, 12, 19 Psychoanalytic Perspectives on Ulcerative Colitis at the Baltimore-D.C. Psychoanalytic Institute, 821 N. Charles St., Baltimore. First in a series of presentations on Classical Psychosomatic Disorders. 8–9:30 p.m.; 4.5 AMA Cat I credits for program. Mar 5: Review of Important Literature; Mar 12: Implications for Medical Management; Mar 19: Participants opportunity to discuss cases. Info/registration 301-727-1740.

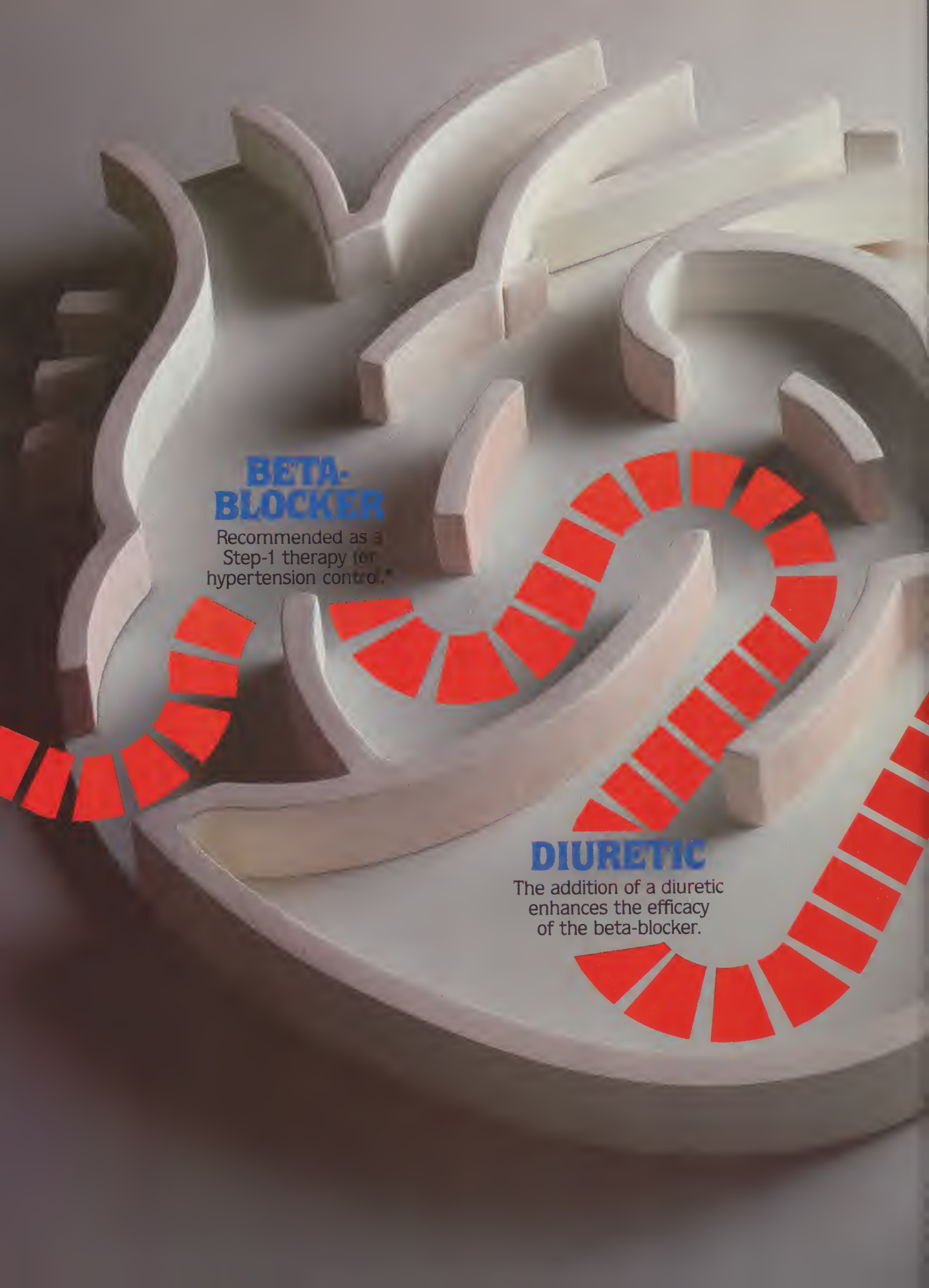
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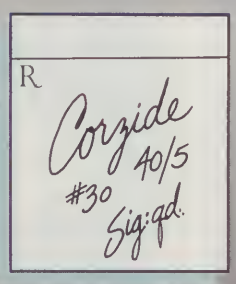
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*Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure. The 1984 report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure. Arch Intern Med 144:1045-1057, 1984.

Please see brief summary of prescribing information on following page

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Nadolol-Bendroflumethiazide Tablets

DESCRIPTION: CORZIDE (Nadolol-Bendroflumethiazide Tablets) for oral administration combines two antihypertensive agents: CORGARD® (nadolol), a nonselective beta-adrenergic blocking agent, and NATURETIN® (bendroflumethiazide), a thiazide diuretic-antihypertensive. Formulations: 40 mg and 80 mg nadolol per tablet combined with 5 mg bendroflumethiazide.

CONTRAINDICATIONS: Nadolol — Bronchial asthma, sinus bradycardia and greater than first degree conduction block, cardiogenic shock, and overt cardiac failure (see WARNINGS). **Bendroflumethiazide** — Anuria, and in those with previous hypersensitivity to bendroflumethiazide or other sulfonamide-derived drugs.

WARNINGS: Nadolol — Cardiac Failure — Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta-blockade may precipitate more severe failure. Although beta-blockers should be avoided in overt congestive heart failure, if necessary, they can be used with caution in patients with a history of failure who are well compensated, usually with digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle. IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta-blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, digitalize and/or give diuretics, and closely observe response, or discontinue nadolol (gradually, if possible).

Exacerbation of Ischemic Heart Disease Following Abrupt Withdrawal — Hypersensitivity to catecholamines has been observed in patients withdrawn from beta-blocker therapy; exacerbation of angina and, in some cases, myocardial infarction have occurred after *abrupt* discontinuation of such therapy. When discontinuing chronic use of nadolol, particularly in patients with ischemic heart disease, gradually reduce dosage over a 1- to 2-week period and carefully monitor the patient. Reinstitute nadolol promptly (at least temporarily) and take other measures appropriate for management of unstable angina if angina markedly worsens or acute coronary insufficiency develops. Warn patients not to interrupt or discontinue therapy without physician's advice. Because coronary artery disease is common and may be unrecognized, it may be prudent not to discontinue nadolol therapy abruptly even in patients treated only for hypertension.

Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema) — PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA-BLOCKERS. Administer nadolol with caution since it may block bronchodilation produced by endogenous or exogenous catecholamine stimulation of β_2 receptors. **Major Surgery** — Because beta blockade impairs the ability of the heart to respond to reflex stimuli and may increase the risks of general anesthesia and surgical procedures, resulting in protracted hypotension or low cardiac output, it has generally been suggested that such therapy should be withdrawn several days prior to surgery. Recognition of the increased sensitivity to catecholamines of patients recently withdrawn from beta-blocker therapy, however, has made this recommendation controversial. If possible, withdraw beta-blockers well before surgery takes place. In emergency surgery, inform the anesthesiologist that the patient is on beta-blocker therapy. Use of beta-receptor agonists such as isoproterenol, dopamine, dobutamine, or levarterenol can reverse the effects of nadolol. Difficulty in restarting and maintaining the heart beat has also been reported with beta-adrenergic receptor blocking agents. **Diabetes and Hypoglycemia** — Beta-adrenergic blockade may prevent the appearance of premonitory signs and symptoms (e.g., tachycardia and blood pressure changes) of acute hypoglycemia. This is especially important with labile diabetics. Beta-blockade also reduces release of insulin in response to hyperglycemia; therefore, it may be necessary to adjust dose of antidiabetic drugs. **Thyrotoxicosis** — Beta-adrenergic blockade may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism. To avoid abrupt withdrawal of beta-adrenergic blockade which might precipitate a thyroid storm, carefully manage patients suspected of developing thyrotoxicosis.

Bendroflumethiazide — Use with caution in severe renal disease. In patients with renal disease, azotemia may be precipitated. With impaired renal function, effects of the drug may be cumulative. Use with caution in impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma. Sensitivity reactions may occur in patients with a history of allergy or bronchial asthma. Possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

PRECAUTIONS: General — Nadolol — Use with caution in patients with impaired hepatic or renal function (see DOSAGE AND ADMINISTRATION).

Bendroflumethiazide — At appropriate intervals, perform serum electrolytes determination to detect possible electrolyte imbalance warning signs of which are dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and G.I. disturbances such as nausea and vomiting. Observe patients for clinical signs of fluid or electrolyte imbalance; namely, hyponatremia, hypochloremic alkalosis, hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Drugs such as digitalis may influence serum electrolytes. Hypokalemia may develop, especially with brisk diuresis, in presence of severe cirrhosis. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Response of the heart to toxic effects of digitalis can be exaggerated with hypokalemia. Use potassium supplements such as high potassium foods to avoid or treat hypokalemia. Any chloride deficit is generally mild and usually does not require specific therapy except under extraordinary circumstances (as in liver or renal disease). Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction rather than salt administration except in rare instances when the hyponatremia is life threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain thiazide-treated patients. Latent diabetes mellitus may become manifest during thiazide therapy. Antihypertensive effects of bendroflumethiazide may be enhanced in the postsympathectomy patient.

Careful reappraisal of therapy and consideration given to withholding or stopping diuretic therapy is necessary if rising nonprotein nitrogen or BUN (indicative of progressive renal impairment) occurs. Thiazides may decrease serum PBI levels without signs of thyroid disturbance. Thiazides decrease calcium excretion. Pathologic changes in parathyroid gland with hypercalcemia and hypophosphatemia have been occasionally observed with prolonged therapy. Common complications of hyperparathyroidism have not been seen.

Information for Patients — Warn patients, especially those with evidence of coronary artery insufficiency, against interruption or discontinuation of nadolol without physician's advice. Although cardiac failure rarely occurs in properly selected patients, advise patients being treated with beta-adrenergic blocking agents to consult physician at the first sign or symptom of impending failure. Advise patients of proper course if dose inadvertently missed.

Laboratory Tests — Regularly monitor serum and urine electrolyte levels (see WARNINGS, *Bendroflumethiazide,* and PRECAUTIONS, *General, Bendroflumethiazide).*

Drug Interactions — Nadolol — When administered concurrently the following drugs may interact with beta-adrenergic blocking agents: **Anesthetics, general** — exaggeration of anesthetic-induced hypotension (see WARNINGS, *Nadolol, Major Surgery).* **Antidiabetic drugs (oral agents and insulin)** — hyperglycemia or hyperglycemia; adjust antidiabetic drug dosage accordingly (see WARNINGS, *Nadolol, Diabetes and Hypoglycemia).* **Catecholamine-depleting drugs (e.g., reserpine)** — additive effect; monitor closely for evidence of hypotension and/or excessive bradycardia.

Bendroflumethiazide — When administered concurrently the following drugs may interact with thiazide diuretics: **Alcohol, barbiturates, or narcotics** — may potentiate orthostatic hypotension. **Antidiabetic drugs (oral agents and insulin)** — thiazide-induced hyperglycemia may require adjustment of antidiabetic drug dosage. **Other antihypertensive drugs** — additive or potentiated effect. **Corticosteroids, ACTH** — intensified electrolyte depletion, particularly hypokalemia. **Ganglionic or peripheral adrenergic blocking drugs** — potentiated effect. **Preanesthetic and anesthetic agents** — effects may be potentiated, adjust dosage accordingly. **Pressor amines (e.g., norepinephrine)** — possible decrease response but not sufficient to preclude their use. **Skeletal muscle relaxants, nondepolarizing (e.g., tubocurarine)** — possible increased response.

Drug/Laboratory Test Interactions — Discontinue thiazides before tests for parathyroid function (see PRECAUTIONS, *General, Bendroflumethiazide).*

Carcinogenesis, Mutagenesis, Impairment of Fertility — Nadolol — In 1 to 2 years oral toxicologic studies in mice, rats, and dogs, nadolol did not produce significant toxic effects. In 2-year oral carcinogenic studies in rats and mice, nadolol did not produce neoplastic, preneoplastic, or nonneoplastic pathologic lesions. **Bendroflumethiazide** — Long-term studies in animals have not been performed.

Pregnancy — Teratogenic Effects — Nadolol — Category C. In animal reproduction studies with nadolol, evidence of embryo- and fetotoxicity was found in rabbits, but not in rats or hamsters, at doses 5 to 10 times greater (on a mg/kg basis) than the maximum indicated human dose; no teratogenic potential was seen in any of these species. There are no well-controlled studies in pregnant women; therefore, use nadolol in pregnant women only if potential benefit justifies potential risk to the fetus. **Bendroflumethiazide** — Category C. Animal reproduction studies have not been conducted. This drug's effect on the fetus when administered to a pregnant woman or its effect on reproductive capacity is not known. Bendroflumethiazide should be given to a pregnant woman only if clearly needed. **Nonteratogenic Effects** — Since thiazides cross the placental barrier and appear in cord blood, weigh anticipated benefit of the drug in pregnant women against possible hazards to the fetus; these hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other reactions which have occurred in adults.

Nursing Mothers — Both nadolol and bendroflumethiazide are excreted in human milk. Because of the potential for serious adverse reactions in nursing infants either discontinue nursing or discontinue therapy, taking into account the importance of CORZIDE (Nadolol-Bendroflumethiazide Tablets) to the mother.

Pediatric Use — Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Nadolol — Most adverse effects have been mild and transient and have rarely required nadolol withdrawal. **Cardiovascular** — Bradycardia with heart rates of less than 60 beats per minute occurs commonly, and heart rates below 40 beats per minute and/or symptomatic bradycardia were seen in about 2 of 100 patients. Symptoms of peripheral vascular insufficiency, usually of the Raynaud type, have occurred in approximately 2 of 100 patients. Cardiac failure, hypotension, and rhythm/conduction disturbances have each occurred in about 1 of 100 patients. Single instances of first degree and third degree heart block have been reported; intensification of AV block is a known effect of beta-blockers (see also CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS). **Central Nervous System** — Dizziness or fatigue reported in approximately 2 of 100 patients; paresthesias, sedation, and change in behavior reported in approximately 6 of 1000 patients. **Respiratory** — Bronchospasm reported in approximately 1 of 1000 patients (see CONTRAINDICATIONS and WARNINGS). **Gastrointestinal** — Nausea, diarrhea, abdominal discomfort, constipation, vomiting, indigestion, anorexia, bloating, and flatulence each reported in 1 to 5 of 1000 patients. **Miscellaneous** — Each of the following reported in 1 to 5 of 1000 patients: rash; pruritus; headache; dry mouth, eyes, or skin; impotence or decreased libido; facial swelling; weight gain; slurred speech; cough; nasal stuffiness; sweating; tinnitus; blurred vision. Although relationship to drug usage is not clear, sleep disturbances have been reported. The oculomucocutaneous syndrome associated with practolol has not been reported with nadolol. The following adverse reactions may also occur: **Central Nervous System** — reversible mental depression progressing to catatonia; visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss; emotional lability with slightly clouded sensorium, decreased performance on neuropsychometrics. **Gastrointestinal** — mesenteric arterial thrombosis; ischemic colitis. **Hematologic** — agranulocytosis; thrombocytopenic or nonthrombocytopenic purpura. **Allergic** — fever combined with aching and sore throat; laryngospasm, respiratory distress. **Miscellaneous** — reversible alopecia; Peyronie's disease; erythematous rash; arterial insufficiency.

Bendroflumethiazide — Gastrointestinal System — anorexia, gastric irritation, nausea, vomiting, cramping, diarrhea, constipation, jaundice (intrahepatic cholestatic jaundice), pancreatitis. **Central Nervous System** — dizziness, vertigo, paresthesia, headache, xanthopsia. **Hematologic** — leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia. **Dermatologic-Hypersensitivity** — purpura, photosensitivity, rash, urticaria, necrotizing angiitis (vasculitis, cutaneous vasculitis). **Cardiovascular** — orthostatic hypotension may occur. **Other** — hyperglycemia, glycosuria, occasional metabolic acidosis in diabetics, hyperuricemia, allergic glomerulonephritis, muscle spasm, weakness, restlessness. Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy withdrawn.

OVERDOSAGE: Nadolol may cause excessive bradycardia, cardiac failure, hypotension, or bronchospasm if overdosed. Overdosage of thiazides may cause lethargy, which may progress to coma within a few hours, with minimal depression of respiration and cardiovascular function and without evidence of serum electrolyte changes or dehydration. Gastrointestinal irritation and hypermotility may occur. Transitory increase in BUN and serum electrolyte changes may occur, especially in patients with renal impairment.

Treatment — Nadolol can be removed from the general circulation by hemodialysis. In determining duration of corrective therapy, take note of the long duration of the effect of nadolol. In addition to gastric lavage, employ the following measures, as appropriate. **Excessive Bradycardia** — Administer atropine (0.25 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously. **Cardiac Failure** — Administer a digitalis glycoside and diuretic. It has been reported that glucagon may also be useful in this situation. **Hypotension** — Administer vasopressors, e.g., epinephrine or levarterenol. (There is evidence that epinephrine may be the drug of choice.) **Bronchospasm** — Administer a β_2-stimulating agent and/or a theophylline derivative. **Stupor or Coma** — Supportive therapy as warranted. **Gastrointestinal Effects** — Symptomatic treatment as needed. **BUN and/or Serum Electrolyte Abnormalities** — Institute supportive measures as required to maintain hydration, electrolyte balance, respiration, and cardiovascular and renal function.

DOSAGE AND ADMINISTRATION: DOSAGE MUST BE INDIVIDUALIZED. Patients with renal failure require adjustment in dosing interval; see package insert for dosage in these patients.

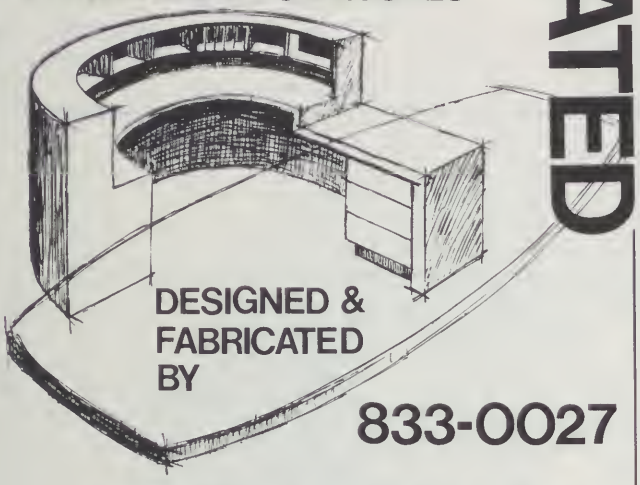
Consult package insert before prescribing CORZIDE (Nadolol-Bendroflumethiazide Tablets).

HOW SUPPLIED: Available as scored tablets containing 40 mg nadolol combined with 5 mg bendroflumethiazide and 80 mg nadolol combined with 5 mg bendroflumethiazide in bottles of 100

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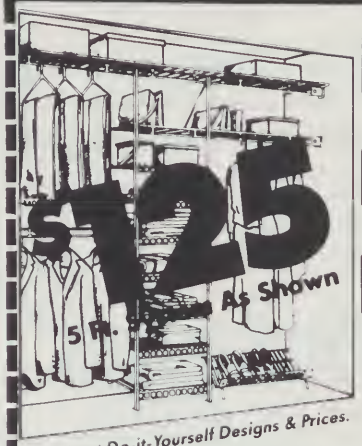
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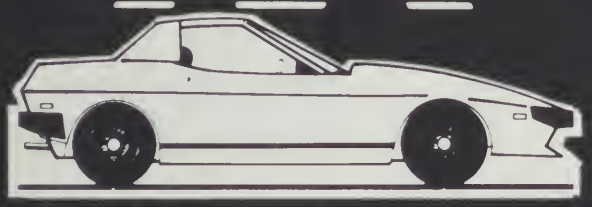
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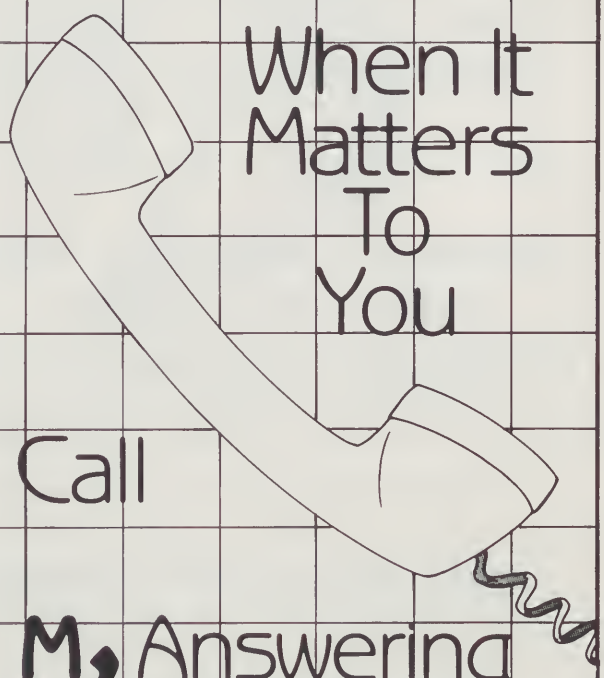


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CARDIZEM® (diltiazem HCl) produces an incidence of adverse reactions not greater than that reported with placebo therapy, thus contributing to the patient's sense of well-being.

*Cardizem is indicated in the treatment of angina pectoris due to coronary artery spasm and in the management of chronic stable angina (classic effort-associated angina) in patients who cannot tolerate therapy with beta-blockers and/or nitrates or who remain symptomatic despite adequate doses of these agents.

References:
1. Strauss WE, McIntyre KM, Parisi AF, et al: Safety and efficacy of diltiazem hydrochloride for the treatment of stable angina pectoris: Report of a cooperative clinical trial. Am J Cardiol 49:560-566, 1982.
2. Pool PE, Seagren SC, Bonanno JA, et al: The treatment of exercise-inducible chronic stable angina with diltiazem: Effect on treadmill exercise. Chest 78 (July suppl):234-238, 1980.

Reduces angina attack frequency*
42% to 46% decrease reported in multicenter study.[1]

Increases exercise tolerance*
In Bruce exercise test,[2] control patients averaged 8.0 minutes to onset of pain; Cardizem patients averaged 9.8 minutes ($P<.005$).

CARDIZEM®
(diltiazem HCl)

THE BALANCED CALCIUM CHANNEL BLOCKER

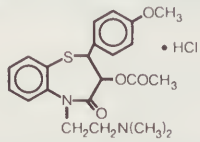
Please see full prescribing information on following page.

PROFESSIONAL USE INFORMATION

cardizem®
(diltiazem HCl)
30 mg and 60 mg tablets

DESCRIPTION

CARDIZEM® (diltiazem hydrochloride) is a calcium ion influx inhibitor (slow channel blocker or calcium antagonist). Chemically, diltiazem hydrochloride is 1,5-Benzothiazepin-4(5H)one,3-(acetyloxy) -5-[2-(dimethylamino)ethyl]-2,3-dihydro-2-(4-methoxyphenyl)-, monohydrochloride,(+) -cis-. The chemical structure is:



Diltiazem hydrochloride is a white to off-white crystalline powder with a bitter taste. It is soluble in water, methanol, and chloroform. It has a molecular weight of 450.98. Each tablet of CARDIZEM contains either 30 mg or 60 mg diltiazem hydrochloride for oral administration.

CLINICAL PHARMACOLOGY

The therapeutic benefits achieved with CARDIZEM are believed to be related to its ability to inhibit the influx of calcium ions during membrane depolarization of cardiac and vascular smooth muscle.

Mechanisms of Action. Although precise mechanisms of its antianginal actions are still being delineated, CARDIZEM is believed to act in the following ways:

1. Angina Due to Coronary Artery Spasm: CARDIZEM has been shown to be a potent dilator of coronary arteries both epicardial and subendocardial. Spontaneous and ergonovine-induced coronary artery spasm are inhibited by CARDIZEM.
2. Exertional Angina: CARDIZEM has been shown to produce increases in exercise tolerance, probably due to its ability to reduce myocardial oxygen demand. This is accomplished via reductions in heart rate and systemic blood pressure at submaximal and maximal exercise work loads.

In animal models, diltiazem interferes with the slow inward (depolarizing) current in excitable tissue. It causes excitation-contraction uncoupling in various myocardial tissues without changes in the configuration of the action potential. Diltiazem produces relaxation of coronary vascular smooth muscle and dilation of both large and small coronary arteries at drug levels which cause little or no negative inotropic effect. The resultant increases in coronary blood flow (epicardial and subendocardial) occur in ischemic and nonischemic models and are accompanied by dose-dependent decreases in systemic blood pressure and decreases in peripheral resistance.

Hemodynamic and Electrophysiologic Effects. Like other calcium antagonists, diltiazem decreases sinoatrial and atrioventricular conduction in isolated tissues and has a negative inotropic effect in isolated preparations. In the intact animal, prolongation of the AH interval can be seen at higher doses.

In man, diltiazem prevents spontaneous and ergonovine-provoked coronary artery spasm. It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure and, in exercise tolerance studies in patients with ischemic heart disease, reduces the heart rate-blood pressure product for any given work load. Studies to date, primarily in patients with good ventricular function, have not revealed evidence of a negative inotropic effect; cardiac output, ejection fraction, and left ventricular end diastolic pressure have not been affected. There are as yet few data on the interaction of diltiazem and beta-blockers. Resting heart rate is usually unchanged or slightly reduced by diltiazem.

Intravenous diltiazem in doses of 20 mg prolongs AH conduction time and AV node functional and effective refractory periods approximately 20%. In a study involving single oral doses of 300 mg of CARDIZEM in six normal volunteers, the average maximum PR prolongation was 14% with no instances of greater than first-degree AV block. Diltiazem-associated prolongation of the AH interval is not more pronounced in patients with first-degree heart block. In patients with sick sinus syndrome, diltiazem significantly prolongs sinus cycle length (up to 50% in some cases).

Chronic oral administration of CARDIZEM in doses of up to 240 mg/day has resulted in small increases in PR interval, but has not usually produced abnormal prolongation. There were, however, three instances of second-degree AV block and one instance of third-degree AV block in a group of 959 chronically treated patients.

Pharmacokinetics and Metabolism. Diltiazem is absorbed from the tablet formulation to about 80% of a reference capsule and is subject to an extensive first-pass effect, giving an absolute bioavailability (compared to intravenous dosing) of about 40%. CARDIZEM undergoes extensive hepatic metabolism in which 2% to 4% of the unchanged drug appears in the urine. In vitro binding studies show CARDIZEM is 70% to 80% bound to plasma proteins. Competitive ligand binding studies have also shown CARDIZEM binding is not altered by therapeutic concentrations of digoxin, hydrochlorothiazide, phenylbutazone, propranolol, salicylic acid, or warfarin. Single oral doses of 30 to 120 mg of CARDIZEM result in detectable plasma levels within 30 to 60 minutes and peak plasma levels two to three hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3.5 hours. Desacetyl diltiazem is also present in the plasma at levels of 10% to 20% of the parent drug and is 25% to 50% as potent a coronary vasodilator as diltiazem. Therapeutic blood levels of CARDIZEM appear to be in the range of 50 to 200 ng/ml. There is a departure from dose-linearity when single doses above 60 mg are given; a 120-mg dose gave blood levels three times that of the 60-mg dose. There is no information about the effect of renal or hepatic impairment on excretion or metabolism of diltiazem.

INDICATIONS AND USAGE

1. **Angina Pectoris Due to Coronary Artery Spasm.** CARDIZEM is indicated in the treatment of angina pectoris due to coronary artery spasm. CARDIZEM has been shown effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (resting angina with ST-segment elevation occurring during attacks).
2. **Chronic Stable Angina (Classic Effort-Associated Angina).** CARDIZEM is indicated in the management of chronic stable angina. CARDIZEM has been effective in controlled trials in reducing angina frequency and increasing exercise tolerance.

There are no controlled studies of the effectiveness of the concomitant use of diltiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities.

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

1. **Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
2. **Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
3. **Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
4. **Acute Hepatic Injury.** In rare instances, patients receiving CARDIZEM have exhibited reversible acute hepatic injury as evidenced by moderate to extreme elevations of liver enzymes. (See PRECAUTIONS and ADVERSE REACTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS).

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vitro bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outweigh its potential risks in this situation.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences, as well as their frequency of presentation, are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%), AV block (1.1%). In addition, the following events were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrence.

Cardiovascular:	Flushing, arrhythmia, hypotension, bradycardia, palpitations, congestive heart failure, syncope.
Nervous System:	Paresthesia, nervousness, somnolence, tremor, insomnia, hallucinations, and amnesia.
Gastrointestinal:	Constipation, dyspepsia, diarrhea, vomiting, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH.
Dermatologic:	Pruritus, petechiae, urticaria, photosensitivity.
Other:	Polyuria, nocturia.

The following additional experiences have been noted:

A patient with Prinzmetal's angina experiencing episodes of vasospastic angina developed periods of transient asymptomatic asystole approximately five hours after receiving a single 60-mg dose of CARDIZEM.

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: erythema multiforme; leukopenia; and extreme elevations of alkaline phosphatase, SGOT, SGPT, LDH, and CPK. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

OVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with oral diltiazem has been limited. Single oral doses of 300 mg of CARDIZEM have been well tolerated by healthy volunteers. In the event of overdosage or exaggerated response, appropriate supportive measures should be employed in addition to gastric lavage. The following measures may be considered:

Bradycardia	Administer atropine (0.60 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.
High-Degree AV Block	Treat as for bradycardia above. Fixed high-degree AV block should be treated with cardiac pacing.
Cardiac Failure	Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics.
Hypotension	Vasopressors (eg, dopamine or levarterenol bitartrate).

Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating physician.

The oral/LD_{50}'s in mice and rats range from 415 to 740 mg/kg and from 560 to 810 mg/kg, respectively. The intravenous LD_{50}s in these species were 60 and 38 mg/kg, respectively. The oral LD_{50} in dogs is considered to be in excess of 50 mg/kg, while lethality was seen in monkeys at 360 mg/kg. The toxic dose in man is not known, but blood levels in excess of 800 ng/ml have not been associated with toxicity.

DOSAGE AND ADMINISTRATION

Exertional Angina Pectoris Due to Atherosclerotic Coronary Artery Disease or Angina Pectoris at Rest Due to Coronary Artery Spasm. Dosage must be adjusted to each patient's needs. Starting with 30 mg four times daily, before meals and at bedtime, dosage should be increased gradually (given in divided doses three or four times daily) at one- to two-day intervals until optimum response is obtained. Although individual patients may respond to any dosage level, the average optimum dosage range appears to be 180 to 240 mg/day. There are no available data concerning dosage requirements in patients with impaired renal or hepatic function. If the drug must be used in such patients, titration should be carried out with particular caution.

Concomitant Use With Other Antianginal Agents:

1. **Sublingual NTG** may be taken as required to abort acute anginal attacks during CARDIZEM therapy.
2. **Prophylactic Nitrate Therapy**—CARDIZEM may be safely coadministered with short- and long-acting nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.
3. **Beta-blockers.** (See WARNINGS and PRECAUTIONS.)

HOW SUPPLIED

Cardizem 30-mg tablets are supplied in bottles of 100 (NDC 0088-1771-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1771-49). Each green tablet is engraved with MARION on one side and 1771 engraved on the other. CARDIZEM 60-mg scored tablets are supplied in bottles of 100 (NDC 0088-1772-47) and in Unit Dose Identification Paks of 100 (NDC 0088-1772-49). Each yellow tablet is engraved with MARION on one side and 1772 on the other.

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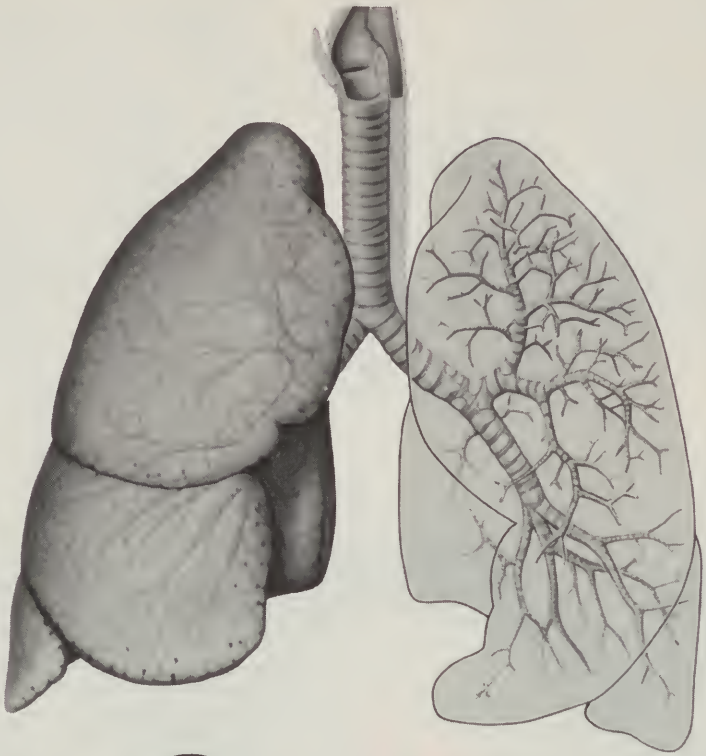
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Brief Summary. Consult the package literature for prescribing information.

Indications and Usage: Ceclor® (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae), Haemophilus influenzae*, and *S. pyogenes* (group A beta-hemolytic streptococci).

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor.

Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Precautions: *General Precautions* — If an allergic reaction to Ceclor® (cefaclor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape® (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy — *Pregnancy Category B* — Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor® (cefaclor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers — Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Ceclor is administered to a nursing woman.

Usage in Children — Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below.

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbilliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic — Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic — Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal — Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[0617B2R]

Note: Ceclor® (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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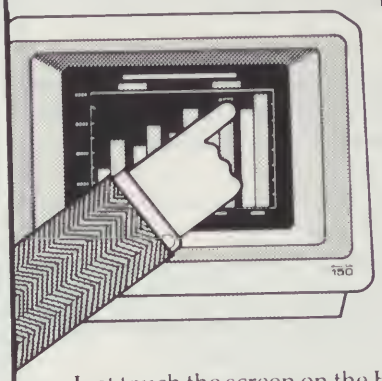
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Advertisers' Index

Associated Speech & Language Services 1022
Ayerst Laboratories 987
Bank of Baltimore 941
Blue Cross & Blue Shield of Maryland 936
Business Automation Inc. 1022
Campbell Laboratories 966
The Carousel Hotel 1014
Cellular One 963
Church Hospital 1030
Cigna 954
Closet Masters 1021
Consultative Examinations Inc. 1030
Crystal Hill Investments, Inc. 954
Curtis 1000 938
Davis Leasing Corporation 1027
Diagnostic Assay Services Inc. 937
Elcomp Systems 940
Elkridge Estates 1033
Epic Residential Network Inc. 1029
Family Home Care 1029
Foto Finishers Inc. 1022
GMC Truck Center 1012
Gordon & Heneson, PA 1002
Grady Management Inc. 1013
Drs. Groover, Christie & Merritt, Partnership 1014
Gucci 959
Heron Harbour Isle 951
Hidden Brook Treatment Center 942
E.F. Hutton 996
Intracare Corp. 939
JBA Leasing 1032
Jerry's Toyota 952
Kipp & Son 962
Knoll Pharmaceutical 968
Koons Porsche Audi 961
Eli Lilly 1026
Marion Laboratories 1023
Maryland Army National Guard 1010
Maryland Medical Laboratories 933
Maryland Office System 1032
Maryland Realtors 965
M-D Answering Service 1021
Med-Chi 954, 1029
Medical Mutual Liability ..... cover 2, 948
Medical Personnel Pool 1012
Medical Resources 1030
Meridian Healthcare 945
Michaelson Motors Inc. 1021
Mountain Manor Treatment Center 966
Multicom Incorporated 1022
National Credit Management Corp. 1012
Old Court Nursing Center 1010
Parke-Davis 943
The Physician and Sportsmedicine 964
physician's resource network inc. 1029
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Roche Laboratories ..... covers 3 & 4
Schumacher & Seiler Inc. 934
Sheppard & Enoch Pratt 953
Sheraton Inner Harbor 946
Smith Kline Beckman 967
South Baltimore General Hospital 1030
E.R. Squibb & Sons 1017
Staff Builders 954
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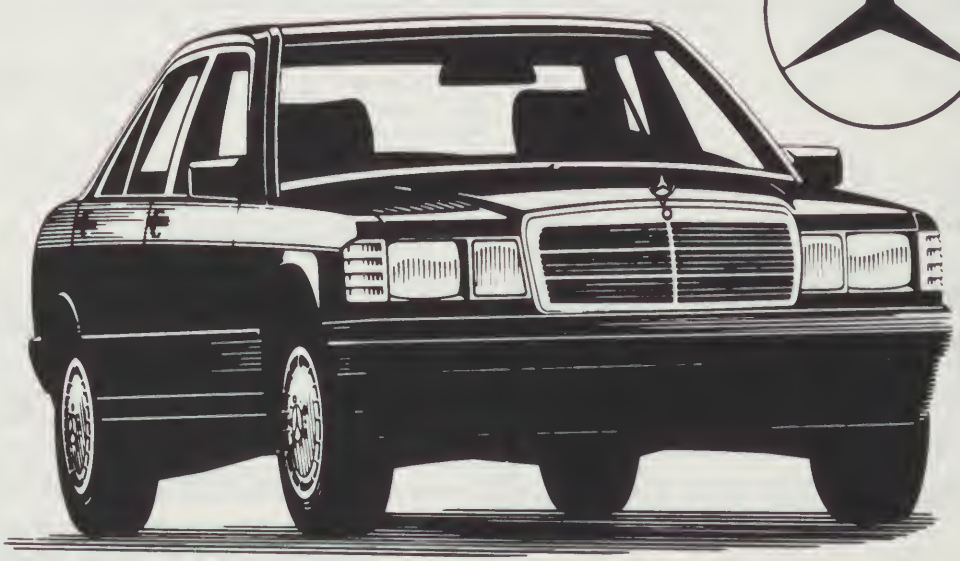
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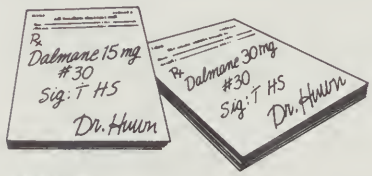
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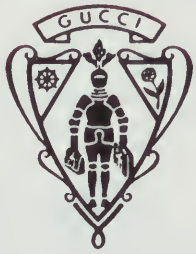
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MISCELLANY

Executive Director's Newsletter 1051
Physicians' Placement Service 1059
Medicolegal Hotline 1075
Medical Miscellany 1086
Hotline Numbers 1087
Change of Address Form 1101
Information for Authors 1121
Doctors Take Note 1122
Classifieds 1125
Advertisers' Index 1127

ARTICLES

CPR: A Survey of Maryland Hospitals—Peter E. Dans MD and Katherine L. Nevin MHS **1073**
Cardiac Arrest: It Happened to Me—Raymond L. Clemmens MD . **1076**
Congenital Cardiovascular Malformations in the Baltimore-Washington Area—Judith D. Rubin MD, Charlotte Ferencz MD, Robert J. McCarter ScD, P. David Wilson PhD, Joann A. Boughman PhD, Joel I. Brenner MD, Catherine A. Neill MD, Lowell W. Perry MD, Seymour I. Hepner MD, and John W. Downing **1079**
The Many Faces of Apical Hypertrophic Cardiomyopathy—Frank W. Davis, Jr., MD **1084**
Osteoarthritis XII: Management of Low Back Pain—A. Lewis Kolodny MD and Jacob Tendler MD **1093**
Dial Access: Call-in Continuing Medical Education—Terrell B. Tanner MD **1101**

DEPARTMENTS

Annual Meeting Announcements **1042**
Maryland Oncology Newsletter **1055**
HBP Commentary **1057**
The Impaired Physician **1059**
One Minute with Diabetes **1060**
Today's Psychiatry **1061**
Disease Control and Epidemiology Newsletter **1063**
The Open Forum **1087**
Your Medical Faculty at Work **1088**
Insurance Monitor **1088**
Auxiliary **1102**
The Library Page **1103**
Discipline Commission Action **1116**

On the cover: Anne Arundel County EMT-Paramedics and a Maryland State Police Aviation Trauma Technician ready a patient for helicopter transport to the Shock Trauma Center. Photo by Robert B. Wright, Bowie Volunteer Fire Department and Rescue Squad.

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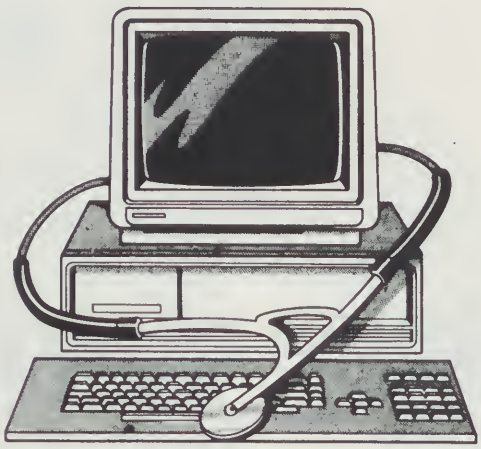
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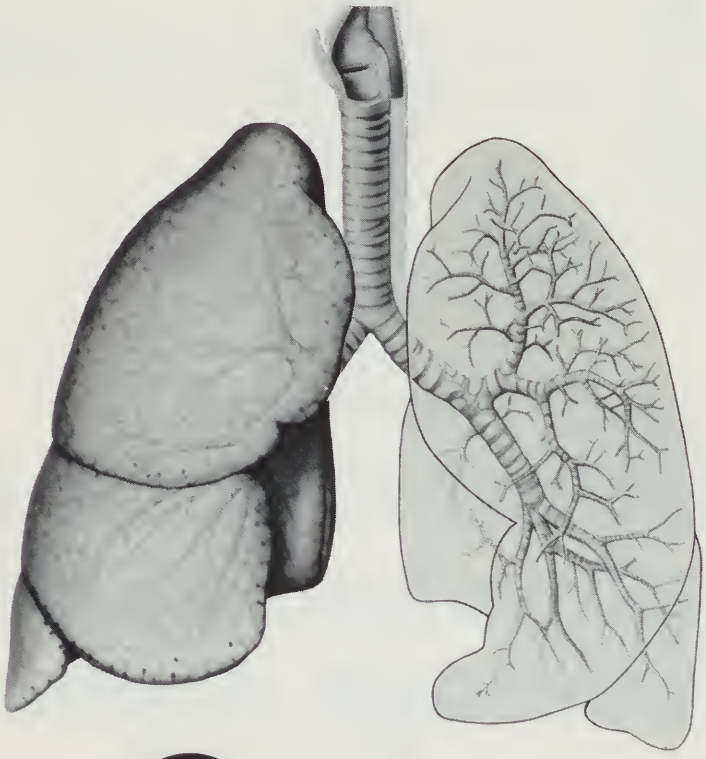
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Brief Summary. Consult the package literature for prescribing information.

Indications and Usage: Ceclor* (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae), Haemophilus influenzae*, and *S. pyogenes* (group A beta-hemolytic streptococci)

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor.

Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Precautions: *General Precautions* — If an allergic reaction to Ceclor* (cefaclor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest* tablets but not with Tes-Tape* (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy — Pregnancy Category B — Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor* (cefaclor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers — Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Ceclor is administered to a nursing woman.

Usage in Children — Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below.

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbilliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic — Slight elevations in SGOT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic — Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal — Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[0617B2R]

Note: Ceclor* (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

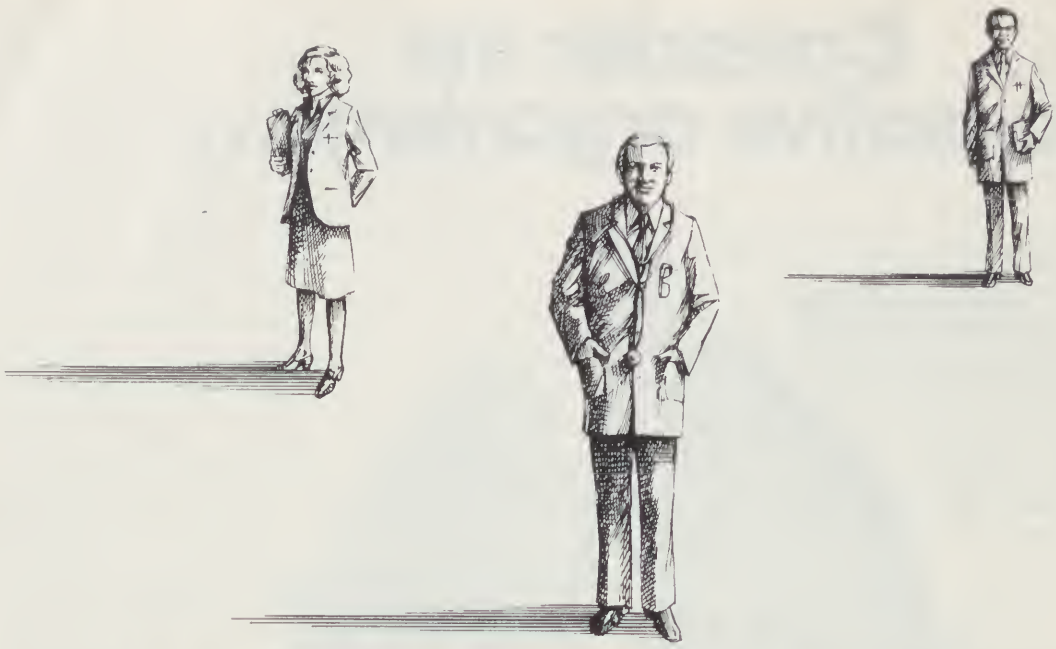
Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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Executive Director's Newsletter

November 1985

JOHN SARGEANT ILL

John Sargeant, Executive Director of the Faculty, is ill. At his request, the Executive Committee has placed him on an indefinite leave of absence.

Pending Mr. Sargeant's return, Elza Davis has been appointed Acting Executive Director. Joseph Harrison, Associate Executive Director, will retain full control of the financial matters of the Faculty, as well as all matters pertaining to the buildings. We hope for Mr. Sargeant's speedy return.

DRUG ALERT

Effective August 27, 1984, Methaqualone was rescheduled from Schedule II to Schedule I. This means that any prescription for this drug, also known as Quaalude, must be pre-authorized by the Federal Drug Enforcement Agency and the Division of Drug Control of the Maryland Department of Health and Mental Hygiene.

MALPRACTICE LIABILITY

The Faculty has begun a public information campaign clearly stating our position on the malpractice crisis in Maryland and encouraging grass-roots support for our efforts. Brochures for your patients are available from the Faculty office and from your county medical or statewide specialty societies. To obtain copies, please call the Faculty office 301-539-0872 or toll-free in Maryland 1-800-492-1056.

On October 9, 1985 the membership was sent an announcement regarding this public awareness campaign and the critical need for malpractice liability reform in Maryland. A contribution of $100 was requested to help fund the campaign.

Many thanks to all who have responded with their support. This campaign is very important and will be very expensive. It is hoped that every member will recognize the need to be united in this effort. If you have not sent your check, please do so right away.

LEGISLATIVE ACTIVITY

The Legislative Committee of the Faculty, chaired by Israel Weiner MD, will discuss and debate the various legislative proposals we will support during the 1986 legislative session. A full report of those discussions will appear in the forthcoming Assemblyman.

A campaign to contact directly each legislator is being coordinated through the county medical societies. If you are interested, please call your county medical society.

TERMINATION OF MEDICAL CARE AND LIVING WILLS

The Council recently adopted guidelines developed by the Committee on Professional Ethics concerning the termination of medical care. Physicians may use these guidelines as a procedural framework within which to make a decision. The guidelines do not discuss substantive medical issues, instead directing physicians to various resources to assist with such decisions. Copies of these guidelines are available from the Faculty office.

Many physicians have received requests from their patients for Living Will forms. You may direct your patients to the Society for the Right to Die, 250 West 57th St., New York, NY 10107. Forms and guidelines are available on request.

UTILIZATION REVIEW REGULATIONS

Although notice of the passage of the utilization review bill, part of the Governor's cost containment package of 1985, was given in the Assemblyman, the real impact of this legislation has now been felt with the publication of emergency regulations effective October 1, 1985.

Under these regulations, hospitals were required to submit a utilization review plan to the State by October 1, 1985. While each plan must comply with the regulations, there will be differences from hospital to hospital. You should have been notified of the details of the plan by each hospital at which you have privileges. If you have not, I suggest you contact your hospital directly and ask for the details of their plan.

The Faculty commented on the emergency regulations at a public hearing on October 1. The Department of Health and Mental Hygiene will continue to receive comments on the regulations. If you have specific comments regarding the regulations, please send them in writing to Henry Schwartz, Chief, Division of Licensing and Certification, DHMH, 201 W. Preston St., Baltimore, MD 21201. Please be sure to send a copy to Med-Chi, Attn: Judith Wood.

1986 DUES BILLS

The 1986 dues bills will be in the mail to all members at the beginning of December. Physicians are reminded that payment of dues by January 31, 1986 is necessary to qualify for a legal defense panel, as outlined in the Faculty Bylaws.

All dues and assessments are tax-deductible items for physicians.

Acting Executive Director

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Maryland Oncology Newsletter

Cutaneous Melanoma: Differential Diagnosis

Several benign pigmented skin lesions should be differentiated from cutaneous melanoma. Among benign nevi are:

Benign pigmented nevus (also called benign mole) usually has a smooth, even border. The color is uniform and mostly brown. There is no nodularity by palpation. Multiple benign nevi appear during childhood and adolescence, reaching maximum numbers by age 20 and then gradually disappearing to half of their numbers by age 50.

Congenital nevus is a benign small mole seen in children. It should not be removed unless it persists beyond adolescence since it usually disappears spontaneously.

Congenital hairy nevus is a dark skin lesion, brown to black, with heavy hair growth. It can vary greatly in size and has been seen in a variety of locations. It should be surgically excised as it has great propensity to develop into melanoma.

Junctional nevus is a benign mole that shows activity at its margins as it enlarges by extending outward. Such lesions must be surgically removed as melanoma cannot be ruled out.

Halo nevus is characterized by local depigmentation around a benign nevus creating a halo appearance. It is presumed that the normal melanocytes are rejected, a process that may continue until the mole completely disappears. Therefore, the clinical picture may vary from a mole surrounded by a circle of depigmentation to a depigmented spot.

Blue nevus lies deep in the dermis. It usually has a nodular appearance with blue color due to light reflection. They are rarely malignant.

Benign nevi located in palms of hands, soles of feet, or external genitalia should be excised since it has been reported that a fair number of these have junctional activities and can predispose to the development of melanoma.

In addition to the above mentioned nevi, other benign lesions may be pigmented and nodular but can be suspicious of melanoma. Among those are:

Dermatofibroma is a firm, nontender, intradermal nodule. The overlying epidermis can be slightly pigmented. Similarly, *epidermoid cysts* may have some discoloration due to infection or bleeding in the cyst. *Seborrheic* keratoses and simple *warts* may display significant pigmentation, however they appear to be "stuck on" the skin. *Thrombosed hemangiomas* and *pyogenic granulomas* also may appear pigmented secondary to hemosiderin deposit. Glomus bodies are neurofibrous tissue commonly present in the skin overlying bone. However, *glomus tumors* can be detected most often on the extremities and nail beds. They have a bluish tinge and can be tender.

Subungual hematomas usually can be diagnosed by the history of trauma and the presence of pain. They can be distinguished from subungual melanoma by the lack of paronechial pigment or linear pigment distribution in the nailbed.

Senile hemangiomas consist of venous lakes that occur in the mucosa of the lower lip and oral cavity. These can be differentiated from mucosal melanoma by pressing on them, which results in blanching and temporary disappearance of the venous blood and the color.

Juvenile melanoma is a misnomer for a benign nodular skin lesion that is commonly seen in juveniles and teenagers. It is usually pale brown and occurs mainly in the face. The pathologist should be informed of the clinical details to avoid overreading the pathology.

Two other malignant lesions may cause confusion with the diagnosis of melanoma: *Basal cell carcinomas* may contain melanocytes and produce pigment. The raised edges and the variety in color makes it difficult to distinguish some of these lesions from melanoma. Furthermore, the central ulceration of these lesions that takes place late in its course makes it impossible to differentiate from an ulcerated melanoma. *Kaposi's sarcoma* almost always presents as multiple dark brown or bluish red nodules or plaques which are made up of proliferating capillaries and connective tissue. The most common site is the foot.

The criteria of melanoma discussed in May 1985 issue of this journal are not absolute but should serve principally as guidelines or indications for excision.

Tumor Conference is held weekly on Fridays between 8–9 AM in Room N13E28. This is an open meeting and any physician is welcome to attend. Physicians can present cases, but please call before Friday to obtain time on the schedule for your case and bring the pathological slides with you.

E. GEORGE ELIAS MD
University of Maryland, Surgical Oncology Program

If you have any questions, call or write the Surgical Oncology Program at the University of Maryland Medical System, Room N13E02, Baltimore, Maryland 21201 (301 528-5224).

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*JAMA, Volume 248, No. 3, pages 336-339
Yearbook of Medicine, 1983, pages 66-67
Pediatric Infectious Disease,Volume 3, No. 6, pages 514-517

HBP Commentary

Ambulatory Blood Pressure Monitoring

CAROL LEWIS SCD and R. PATTERSON RUSSELL MD

This begins a series of three commentaries on the state-of-the-art of ambulatory blood pressure monitoring (ABPM).

Lewis is Executive Director, Maryland High Blood Pressure Commission, and Russell is Associate Professor, Johns Hopkins School of Medicine

An increasing body of evidence indicates that single clinical measurements of blood pressure (BP) may not, because of their variability, provide a reliable index for diagnosis of hypertension. Prevalence rates may be reduced by more than half by simply requiring two or more BP measurements. This is particularly true for the large number of individuals who, on initial screening, have a diastolic BP between 90–94 mm Hg. The more borderline the degree of hypertension, the more common the problem of diagnosis and treatment becomes. Furthermore, the zeal with which we are urged to treat patients with milder degrees of hypertension makes more objective methods of measurement imperative. Two alternative ways of measuring BP used most commonly are measurements made by the patient and measurements by ambulatory BP recorders.

Limitations of Office and Home BP Measurement

Office BP measurements, using a standard sphygmomanometer, traditionally have been the principal method of diagnosing hypertension as well as monitoring its treatment.[1] However, substantial evidence dating back to 1940 suggests that office BP measurements may not reliably reflect BP in other settings or during ordinary daily activities and that home BP measurements are typically lower than clinic measurements.[2] The higher clinic pressure readings probably are not due simply to the anxiety of being in the doctor's office (the "white coat" effect) because they are not necessarily accompanied by a higher heart rate and may persist after repeated visits.[3]

Recently there has been a trend toward using patients' self-recorded home BP measurements to circumvent some of the limitations of office measurements. There also has been a great increase in availability of recorders with which patients can take their own BP. Automatic machines are installed in public places such as drugstores and supermarkets, and relatively inexpensive devices are available from discount or mail order houses. Unfortunately, these devices often are inaccurate, and patients usually do not have adequate training in their use. Other limitations include patients' cooperation, compliance, frequency of recordings, and sampling error. Also generally precluded from patient measurement data are pressure readings during sleep, exercise, and other activities.[1]

Ambulatory Blood Pressure Monitoring

One rationale for use of ambulatory blood pressure monitoring (ABPM) is improved documentation of the great daily variability of BP. This variability, associated with changes in activity, has been well-demonstrated by both invasive and noninvasive techniques.[3] Since adverse effects of BP on circulation are thought to depend on the average level of pressure over time or possibly on peak levels of pressure, there is sound reason for thinking that multiple measurements of BP would better predict pressure-related morbid events than a few measurements taken at one time in the day. Techniques for recording BPs in the active ambulatory patient have developed along two lines: direct (intra-arterial) and indirect (noninvasive) 24-hour BP recording.

Direct Intra-arterial Recording In the early 1960s, following reports of BP variability documented by indirect methods, Bevan and coworkers developed a small portable apparatus for continuous direct intra-arterial recording of systolic and diastolic BPs over a period of up to 24 hours. The subject wearing the apparatus was free to move about and the observer was needed only to service the apparatus at 12-hour intervals. The subject maintained a carefully compiled log of events and activities to correlate with changes in blood pressure. Preliminary results in these subjects were reported in 1969.[4] Large variations in pressure were found with different activities and during emotional stress: in most subjects the highest pressure was twice the lowest pressure recorded during the 24 hours. Each subject, normotensive or hypertensive, was in the hypertensive range at some time during the day. Most were also normotensive at some time during the period of observation, even those patients with malignant hypertension. The relatively low pressures that had been observed by others during sleep were confirmed.

Subsequent reports described further development and improvement in the apparatus, using new types of transducers and a miniature analog multichannel tape recorder. It became possible to produce an automatic analysis of the entire 24-hour study for systolic, diastolic, mean BP, and pulse interval. The electrocardiogram (ECG) could be recorded simultaneously. This

HBP Commentary is contributed by the Maryland High Blood Pressure Commission, 201 W. Preston St., Baltimore, MD 21201 (301-225-5891). Editors: R. Patterson Russell MD, Past Chairman; Donald O. Fedder PharmBS, DrPH, Chairman; and Carol Lewis MPH, ScD, Executive Director.

type of apparatus has been used to assess BP changes in both normotensive and hypertensive patients, to differentiate between patients with definite and those with borderline hypertension, and to monitor therapy in severely hypertensive patients.

Indirect (Noninvasive) Recording In 1964 Richardson and coworkers, working with Sir George Pickering, reported the great variability of arterial pressure on hospitalized patients monitored with an oscillographic recorder that measured indirect BP at 5-minute intervals.[5] Recent advances in medical technology have enabled development of portable noninvasive BP recorders that can monitor changes of BP over periods of 24 hours or more.

Indirect noninvasive ambulatory blood pressure recording has employed both automatic and semiautomatic methods. With the semiautomatic type the patient is required to activate the equipment to record each measurement. The automatic models are self-activating, and may be set to record at varying intervals depending on the time of day with less frequent recordings programmed during the sleep cycle to avoid disruption to the patient.

Predictability of Target Organ Damage

Discrepancies that exist between measurement of blood pressure in the clinic and ABPM raise the question of whether clinic or ambulatory readings are more predictive of eventual cardiovascular consequences for the patient. The Framingham Study, The Hypertension Detection and Followup Program, and insurance industry data all show the powerful predictive value of office arterial readings. However, evidence is accumulating that there is an even stronger relationship between ABPM results and prognosis. Studies comparing ABPM and clinic BP readings (in which target organ damage was evaluated by ECG, chest x-ray, and fundal changes) have found ambulatory pressure readings more closely related than were casual readings to overall severity of hypertensive complications.

Cardiac hypertrophy, or left ventricular hypertrophy (LVH), has long been regarded as a significant complication of hypertension. Traditionally the presence or absence of LVH has been ascertained by evaluating chest x-rays and ECGs. More recent studies have shown echocardiography as a predictor of LVH is more sensitive and accurate than is chest x-ray or ECG. Regardless of which criterion is selected to ascertain whether LVH is present, there is a remarkable conformity among studies that have compared ABPM to casual BP recording; ABPM is consistently superior in predicting cardiac hypertrophy.[3]

There is also one published study relating clinical outcome to ambulatory BPs.[6] Although ambulatory and office readings were significantly correlated, the former were more predictive of cardiovascular mortality and morbidity than were the latter, particularly in persons with milder hypertension. This is the first direct evidence that ABPM can discriminate between high-risk and low-risk groups within a given level of office BPs.

Next month we review clinical uses of ABPM and the limitations of this technique.

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The Impaired Physician

It Happens to Doctors, Too

The title is not original. I wish it was: it is very expressive, invites your attention, suggests much about content, yet simultaneously piques your curiosity. "What happens?" "Why does it happen?" "What can we do about it?"

It's a title of a fine small book by Abraham J. Twerski MD. Dr. Twerski is a psychiatrist, medical director of a rehabilitation center for addictive diseases, and one of the founders and former Chairman of the Impaired Physician Committee of the Pennsylvania Medical Society. His book recently was published by Hazelden, Center City, Minnesota.

Seldom does one find as much useful and helpful information in 128 pages. Chapter titles such as "Are Doctors Different?" "What Is an Addict?" "Who Is an Alcoholic?" and "The Futility of Concealment" suggest its worth to all physicians, physicians' spouses, and others concerned about physicians. The text is straightforward, and reads smoothly and easily as the author compellingly makes his case.

For example, writing on attitudes explaining extreme physician resistance to a diagnosis of alcoholism or other chemical dependency, he states, "Since the physician's function and livelihood is completely contingent upon the intact capacity to make correct judgments in the most vital areas of life and health, any condition which can adversely affect judgmental capacity is perceived as extremely threatening and is consequently subject to intense denial."

In the chapter on definitions, Twerski makes the insightful observation that a person who depends on the use of alcohol for the conduct of normal activities (such as working, eating, socializing, having sex, sleeping, and relaxing) "is an alcoholic, even if the quantity of alcohol consumed appears minimal." "Such dependence on alcohol or drugs is the first stage of addiction."

Alcoholic and drug-dependent physicians are not just struck one fine day with full-blown alcoholism or addiction. Twerski lucidly explains the often insidious, relentlessly progressive nature of the completely destructive syndrome that is only toward the end so easily recognized by nearly everyone, including the neighbor's children.

Concerning denial (a major symptom of chemical dependency) he states, "It is most apt to occur when the correct recognition of reality is too threatening to the person." As to loneliness, he writes that alcoholics "have always had a profound conviction that they were somehow different. Understandably enough, when recovery occurs, it is accompanied by . . . the realization that they indeed are *not* different."

It is Dr. Twerski's belief, with which I readily concur, that the "individual escapes into the anesthesia or pseudo-reality of mind-altering substances because he feels himself unable to tolerate or cope with the *normal* stresses of his life." This insight has much relevance to the need for effective therapies other than the traditional psychodynamic approach. The traditional approach that "quests for sources of pathologic anxiety" says Twerski, "is futile since the culprit is the intolerance of *normally* occurring anxiety."

A shorter, clearer, and more concise insight into the complex dynamics of the development of alcoholism in physicians, its recognition and therapy, is not available. The crisply written text has memorable notions in every chapter. For example, "The central nervous system does not discriminate between depressants and/or stimulants obtained at a liquor store, from a drug pusher, or those dispensed by a pharmacist upon prescription by a physician."

Completing the text are several useful case histories and an appendix describing suggested bylaws provisions for hospitals establishing an Impaired Physicians program, as well as the "Georgia Doctor's Test for Adult Alcohol and Drug Use." The latter is useful for self-analysis by the reader or for diagnostic use with a patient or colleague who may be in trouble.

For a small amount of money and a couple of hours of your time you can become reasonably informed on a useful topic of concern to every physician and physician's spouse. A toll-free call to Hazelden Publications (800-328-9000) will procure the book chargeable to your major credit card.

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One Minute with Diabetes

Doctor, My 12-year-old son has had poorly controlled diabetes for two years. We have been to a number of physicians and none of them seem to be able to improve his control. All of them say he has "brittle" diabetes and will have to accept it. What is brittle diabetes and can anything be done to improve the problem?

Webster's dictionary defines brittle as "fragile" and "easily disrupted." It is not really a type of diabetes. About 2 to 10 percent of the insulin dependent (type I) diabetics have wide swings in their diabetic control from bouts of ketosis to episodes of hypoglycemia. These people are called "brittle" diabetics.

With our increasing knowledge of the management of diabetes the number of brittle diabetics is decreasing. Some of the problems causing this condition are:

Treatment errors Taking too much insulin will cause hypoglycemia followed by rebound hyperglycemia and resultant poor control. This can be overcome by reducing the daily dose of insulin by about 10 percent. Sometimes splitting the dose of insulin into an A.M. and P.M. program will produce remarkable improvement in control. Sometimes adding a small amount of regular insulin to the morning or evening dose will be helpful. Remembering the following table will be helpful in monitoring insulin dosage:

Peak Action of Insulin

A.M.	Regular	Noon
A.M.	NPH or Lente	Afternoon
P.M.	Regular	Bedtime
P.M.	NPH or Lente	Fasting

Variation in exercise Exercise should be done regularly. If exercise is at all strenuous it can be compensated for by reducing the insulin dose before the event or increasing carbohydrate intake. Usually it is better to exercise after a meal than before it.

Variation in meal plan Perhaps this is the most common reason for poorly controlled diabetes. The meal plan can be adjusted to as much as six feedings per day if necessary to give a steady balance of caloric intake (particularly the carbohydrates). The total caloric consumption should be within 100 calories of the same amount consumed each day. Often the addition of fiber to the meal plan will lessen the wide swings in glycemic control.

Underlying unrecognized illness

Psychological problems including hidden or selfadministration of insulin

In an adult with this problem, hidden alcoholism must be considered

The wide availability of self-blood glucose monitoring will certainly help in improving glycemic control in these people. If an individual is very cooperative, responsible, reasonably intelligent, and emotionally suited, use of an insulin pump might be considered if other steps are not effective in controlling the "brittle" diabetic patient.

DeWITT E. DeLAWTER **MD**
Editor

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Today's Psychiatry

Antidepressants and the Cardiovascular System

The pharmacotherapy of depression began in 1957 when Imipramine (a tricyclic) and Iproniazide (a monoamine oxidase (MAO) inhibitor) were found to have antidepressive effects. After initial optimism, doubts appeared over their effectiveness and safety. MAO inhibitors presented dangerous, although infrequent, interactions with the tyramine occurring in certain foods. Hypertension crises, sometimes resulting in death, caused withdrawal from the market of several MAO inhibitors; other similar compounds were found safe if diet was controlled for tyramine. A more frequent, although mild, side effect of these drugs was hypotension.

Tricyclics were found to alter EKGs (lengthening of PR, QRS, and QRT), increase heart rate, and induce hypotension. They may cause heart block in patients with pre-existent conduction disease, particularly bundle branch disease; in cases of overdose in noncardiac patients, death from heart block has occurred.

The cardiac risk of the tricyclics was not clarified until recently. Glassman and Bigger[1] demonstrated that the main cardiovascular effect of therapeutic levels of tricyclic antidepressants is hypotension and that in the general population this side effect limits use of these drugs in only 5 percent of the cases. Younger patients seldom present dangerous levels of hypotension; older patients may be subject to falls that could result in lacerations and fractures.

In patients taking diuretics or other cardiovascular drugs the incidence of hypotension increases: in patients with heart failure it may rise to 50 percent. Patients with pre-existing left ventricular dysfunction have an increased occurrence of hypotension; even in these patients tricyclics do not impair the muscular pump function of the heart.[2] Patients with ventricular arrhythmia can receive tricyclics without risk: in fact, tricyclics are highly effective antiarrhythmic agents.

Newer, nontricyclic antidepressants have less cardiovascular side effects. However, ventricular extradepolarization has been reported[3] with trazodone. Until more research is done with the newer antidepressants on cardiac patients, we cannot be confident of their superiority to tricyclics.

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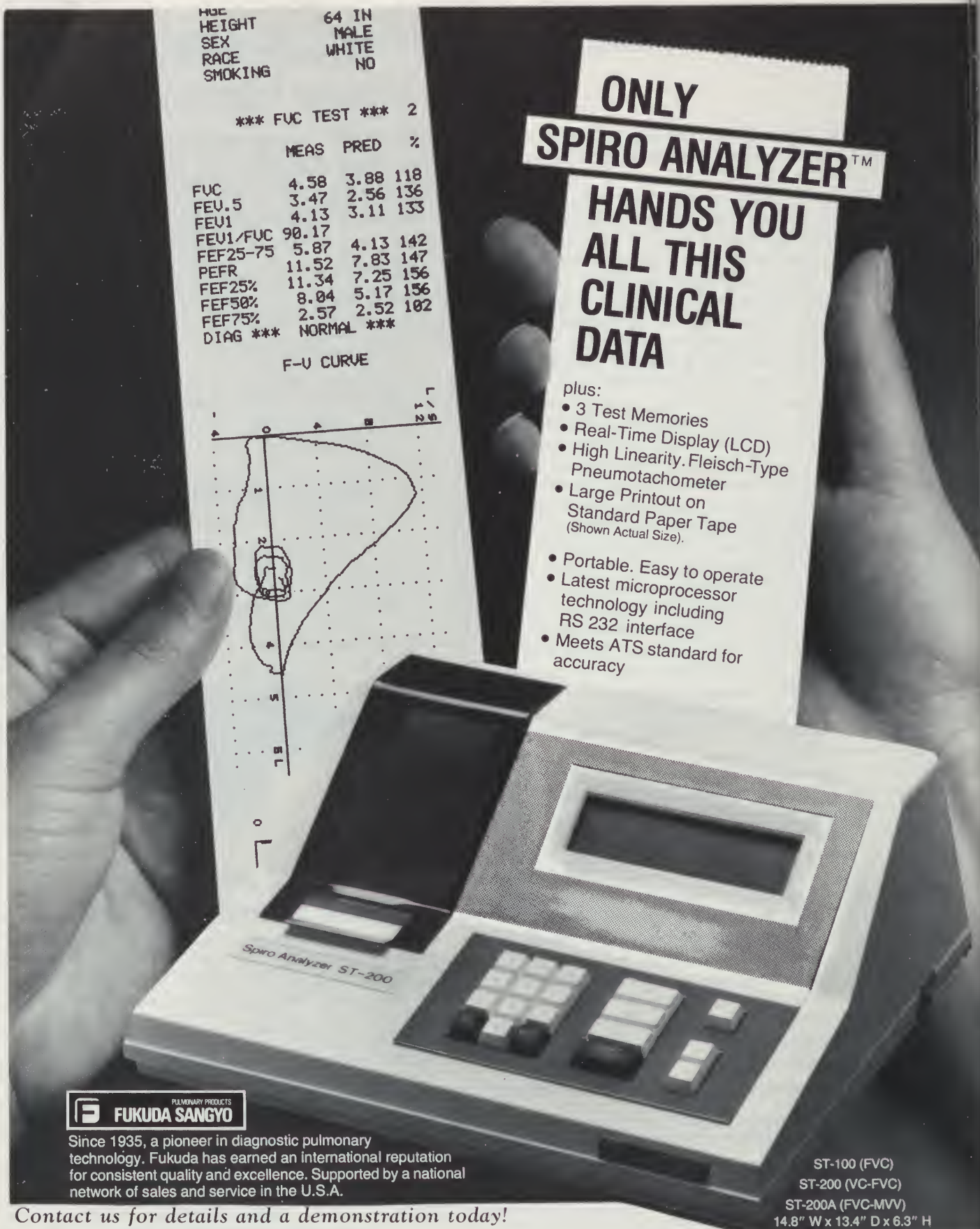
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NOVEMBER 1985

TETRACYCLINE RESISTANT STRAIN(S) OF N. GONORRHOEAE IN MARYLAND

Since September 1984, the Cheverly Branch Laboratory at the Prince George's County Health Department STD Program has been routinely performing Kirby-Bauer sensitivity studies for penicillin and tetracycline on all positive "Tests of cure" cultures (TOC's) on patients who had been treated for gonorrhea. Between September 1984 and May 1985, there was a single isolate which showed an intermediate range zone of inhibition and none which was resistant to tetracycline. In the next 2-3 months, 15 isolates which were resistant to tetracycline were detected. This prompted a study of tetracycline resistance.

Preliminary data from this study of tetracycline resistance in the Prince George's County Health Department STD clinic indicate that 15 of 110 (13.6%) positive cultures for N. gonorrhoeae were markedly resistant to tetracycline. These isolates were very sensitive to penicillin and spectinomycin.

This pattern of antibiotic susceptiblity appears similar to that of the isolates of tetracycline resistant N. gonorrhoeae reported by the CDC in MMWR Vol. 34, No. 37, September 20, 1985. MIC's and auxotyping will be performed on all the resistant isolates to confirm the disc sensitivity study results.

In view of these findings, the Office of Disease Control and Epidemiology recommends that tetracycline alone not be used as an alternative treatment for uncomplicated gonorrhea until more information is available.

DHMH recommended treatment guidelines for uncomplicated urogenital gonorrhea:

Amoxicillin, 3.0 gram or ampicillin, 3.5 gram either of these given with 1.0 gram of probenecid by mouth

OR

Aqueous Procaine Penicillin G 4.8 million units injected intramuscularly (IM) at 2 sites with 1.0 gram of probenecid by mouth.

If treatment for co-existent chlamydia infection is indicated, a regimen combining the above with Tetracycline 500 mg, by mouth, 4 times a day for 7 days may be used.

For treatment of uncomplicated urogenital gonorrhea in penicillin allergic patients, use Spectinomycin 2.0 gram IM in 1 injection.

It is strongly recommended that private physicians intensify their efforts to bring patients treated for gonorrhea back 4-7 days after completion of treatment for Test of Cure cultures.

Plans are being made to extend susceptibility studies to other STD clinics in the State to get a clearer picture of the regional differences in the prevalence of tetracycline resistance in Maryland.

PREVENTION AND CONTROL OF INFLUENZA

TARGET GROUPS FOR VACCINATION:

1. Special efforts should be directed at providing vaccine to those who may derive the greatest benefit. Groups for which active, targeted vaccination efforts are most necessary are:

   a. Adults and children with chronic disorders of the cardiovascular or pulmonary systems that are severe enough to have required regular medical follow-ups or hospitalization during the preceding year.

   b. Residents of nursing homes and other chronic-care facilties (e.g., institutions housing patients of any age with chronic medical conditions).

2. Although not proven, it is reasonable to believe that medical personnel can transmit influenza infections to their high-risk patients while they are themselves incubating infection, undergoing subclinical infection, or working despite the existence of mild symptoms. In many winters, nosocomial outbreaks of influenza are reported. The potential for introducing influenza to high-risk groups, such as patients with severely compromised cardiopulmonary or immune systems or infants in neonatal intensive-care units, should be reduced by vaccination programs targeted at medical personnel. Therefore, physicians, nurses, and other personnel who have extensive contact with high-risk patients (e.g., primary-care and certain specialty clinicians and staff of intensive-care units) should receive influenza vaccination annually.

3. After considering the needs of the above two target groups, high priority should also be given to organizing special programs making vaccine readily available to persons at moderately increased risk of serious illness compared with the general population.

   a. Otherwise healthy individuals over 65 years of age.
   b. Adults and children with chronic metabolic diseases (including diabetes mellitus), renal dysfunction, anemia, immunosuppression, or asthma that are severe enough to require regular medical follow-ups or hospitalization during the preceding year.

GENERAL POPULATION: Physicians should administer vaccine to any persons in their practices who wish to reduce their chances of acquiring influenza infection. Persons who provide essential community services, such as fire and police department employees, and health-care personnel are not considered to be at increased occupational risk of serious influenza illness but may be considered for vaccination programs designed to minimize the possible disruption of essential activities that can occur during severe epidemics.

PREGNANT WOMEN: Pregnancy has not been demonstrated to be a risk factor for severe influenza infection, except in the largest pandemics of 1918-1919 and 1957-1958. Influenza vaccine is considered generally safe for pregnant women. Nonetheless, when vaccine is given during pregnancy, waiting until after the first trimester is a reasonable precaution to minimize any concern over the theoretical possibility of teratogenicity.

PERSONS WHO SHOULD NOT BE VACCINATED: Inactiviated influenza vaccine should not be given to persons who have an anaphylactic sensitivity to eggs (see SIDE EFFECTS AND ADVERSE REACTIONS below). Persons with acute febrile illnesses normally should not be vaccinated until their temporary symptoms have abated.

SIDE EFFECTS AND ADVERSE REACTIONS:

Vaccines used in recent years have generally been associated with only a few reactions, fewer than one-third of vaccinees have been reported to develop local redness or induration for 1 or 2 days at the site of injection.

Systemic reactions have been of two types:

1. Fever, malaise, myalgia, and other systemic symptoms of toxicity, although infrequent, most often affect children and others who have had no exposure to the influenza virus antigens contained in the vaccine. These reactions, which begin 6-12 hours after vaccination and persist for 1-2 days, are usually attributed to the influenza antigens (even though the virus is inactivated) and constitute most of the systemic side effects of influenza vaccination.

2. Immediate, presumably allergic responses, such as flare and wheal or various respiratory tract symptoms of hypersensitivity, occur extremely rarely after influenza vaccination. These symptoms probably result from sensitivity to some vaccine component, most likely residual egg protein. Although current influenza vaccines contain only a small quantity of egg protein, on rare occasions, vaccine can induce hypersensitivity reactions. Individuals with anaphylactic hypersensitivity to eggs should not be given influenza vaccine. Such persons include those who, on eating eggs, develop swelling of the lips or tongue or

experience acute respiratory distress or collapse. Unlike the 1976 swine influenza vaccine, subsequent vaccines have not been associated with an increased frequency of Guillain-Barre syndrome.

It has been reported that influenza vaccination may affect the clearances of warfarin and theophyline. Several studies, however, have failed to show any consistent adverse effect of influenza vaccination on patients taking these drugs.

Influenza vaccine* dosage by age of patient — United States, 1985-1986 season

Age group	Product†	Dosage§	No. doses	Route¶
6-35 mos.	Split virus only	0.25 ml	2**	IM
3-12 yrs.	Split virus only	0.5 ml	2**	IM
> 12 years	Whole or split virus	0.5 ml	1	IM

*Contains 15 μg each of A/Chile/83(H1N1), A/Philippines/82(H3N2), and B/USSR/83 hemagglutinin antigens in each 0.5 ml. Manufacturers include Parke-Davis (Fluogen® split), Squibb-Connaught (Fluzone® whole or split), Wyeth Laboratories (Influenza Virus Vaccine, Trivalent split). Manufacturer's phone numbers to obtain further product information are: Parke-Davis — (800) 223-0432; Squibb-Connaught — (800) 822-2463; Wyeth — (800) 321-2304.

†Because of the lower potential for causing febrile reactions, only split (subvirion) vaccine should be used in children. Immunogenicity and reactogenicity of split and whole virus vaccines are similar in adults when used according to the recommended dosage.

§Pneumococcal vaccine and influenza vaccine can be given at the same time at different sites without an increase in side effects, but it should be emphasized that, whereas influenza vaccine is given annually, pneumococcal vaccine should be given only once to adults. Detailed immunization records should be provided to each patient to help ensure that additional doses of pneumococcal vaccine are not given.

¶The recommended site of vaccination is the deltoid muscle for adults and older children. The preferred site for infants and young children is the anterolateral aspect of the thigh musculature.

**Four weeks or more between doses, both doses recommended for maximum protection. However, if the individual received at least one dose of any influenza vaccine recommended from 1978-1979 to 1984-1985, one dose is sufficient.

Adapted from the Morbidity and Mortality Weekly Report (MMWR), Centers for Disease Control (CDC), May 17, 1985/Vol. 34/No. 19.

CONFERENCE ANNOUNCEMENT

The Office of Disease Control and Epidemiology is presenting a conference, Disease Transmission in the Ambulatory Care Setting on December 17, 1985 at the Baltimore County campus of the University of Maryland. The topics to be discussed include prevention of needlestick injuries, infectious waste disposal, and measles transmission in ambulatory care settings.

Registration is free, but preregistration is required. 4.5 hours of CME credits will be awarded. For further information call Dr. Henry Wasserman or Ms. Pat Powers at (301)-225-6712.

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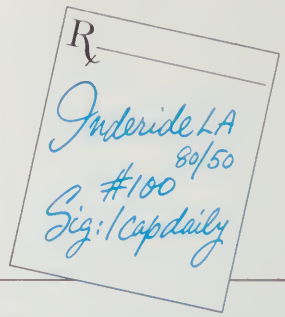
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INDERIDE® LA Brand of **PROPRANOLOL HYDROCHLORIDE (INDERAL® LA) and HYDROCHLOROTHIAZIDE (Long Acting Capsules)**

No. 455—Each INDERIDE® LA 80/50 Capsule contains
Propranolol hydrochloride (INDERAL® LA) 80 mg
Hydrochlorothiazide 50 mg

No. 457—Each INDERIDE® LA 120/50 Capsule contains
Propranolol hydrochloride (INDERAL® LA) 120 mg
Hydrochlorothiazide 50 mg

No. 459—Each INDERIDE® LA 160/50 Capsule contains
Propranolol hydrochloride (INDERAL® LA) 160 mg
Hydrochlorothiazide 50 mg

INDERIDE LA is indicated in the management of hypertension.

This fixed-combination drug is not indicated for initial therapy of hypertension. If the fixed combination represents the dose titrated to the individual patient's needs, therapy with the fixed combination may be more convenient than with the separate components.

CONTRAINDICATIONS

Propranolol hydrochloride (INDERAL®):
Propranolol is contraindicated in: 1) cardiogenic shock, 2) sinus bradycardia and greater than first degree block, 3) bronchial asthma, 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with propranolol.

Hydrochlorothiazide:
Hydrochlorothiazide is contraindicated in patients with anuria or hypersensitivity to this or other sulfonamide-derived drugs.

WARNINGS

Propranolol hydrochloride (INDERAL®):
CARDIAC FAILURE. Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated, and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or propranolol should be discontinued (gradually if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of propranolol therapy. Therefore, when discontinuance of propranolol is planned, the dosage should be gradually reduced and the patient carefully monitored. In addition, when propranolol is prescribed for angina pectoris, the patients should be cautioned against interruption or cessation of therapy without the physician's advice. If propranolol therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute propranolol therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

THYROTOXICOSIS. Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol does not distort thyroid function tests.

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

MAJOR SURGERY. The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

Nonallergic Bronchospasm (eg, chronic bronchitis, emphysema)—PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD, IN GENERAL, NOT RECEIVE BETA BLOCKERS. INDERAL should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

DIABETES AND HYPOGLYCEMIA. Beta-adrenergic blockade may prevent the appearance of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more difficult to adjust the dosage of insulin. Hypoglycemic attacks may be accompanied by a precipitous elevation of blood pressure.

Hydrochlorothiazide:
Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. In patients with impaired renal function, cumulative effects of the drug may develop.

Thiazides should also be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Thiazides may add to or potentiate the action of other antihypertensive drugs. Potentiation occurs with ganglionic or peripheral adrenergic-blocking drugs.

Sensitivity reactions may occur in patients with a history of allergy or bronchial asthma.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

PRECAUTIONS

Propranolol hydrochloride (INDERAL®):
GENERAL. Propranolol should be used with caution in patients with impaired hepatic or renal function. Propranolol is not indicated for the treatment of hypertensive emergencies.

Beta-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should be told that propranolol may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

CLINICAL LABORATORY TESTS. Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS. Patients receiving catecholamine-depleting drugs, such as reserpine, should be closely observed if propranolol is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity, which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY. Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies, in both rats and mice, employing doses up to 150 mg/kg/day there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

PREGNANCY. Pregnancy Category C. Propranolol has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximal recommended human dose. There are no adequate and well-controlled studies in pregnant women. Propranolol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS. Propranolol is excreted in human milk. Caution should be exercised when propranolol is administered to a nursing mother.

PEDIATRIC USE. Safety and effectiveness in children have not been established.

Hydrochlorothiazide:
GENERAL. Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals.

All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance: namely, hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Medication such as digitalis may also influence serum electrolytes. Warning signs, irrespective of cause, are: Dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.

Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present, or during concomitant use of corticosteroids or ACTH.

Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia can sensitize or exaggerate the response of the heart to the toxic effect of digitalis (eg, increased ventricular irritability). Hypokalemia may be avoided or treated by use of potassium supplements, such as foods with a high potassium content.

Any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver or renal disease). Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt, except in rare instances when the hyponatremia is life-threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy.

Insulin requirements in diabetic patients may be increased, decreased, or unchanged. Diabetes mellitus which has been latent may become manifest during thiazide administration.

If progressive renal impairment becomes evident, consider withholding or discontinuing diuretic therapy.

Thiazides may decrease serum PBI levels without signs of thyroid disturbance.

Calcium excretion is decreased by thiazides. Pathologic changes in the parathyroid gland with hypercalcemia and hypophosphatemia have been observed in a few patients on prolonged thiazide therapy. The common complications of hyperparathyroidism, such as renal lithiasis, bone resorption, and peptic ulceration have not been seen. Thiazides should be discontinued before carrying out tests for parathyroid function.

DRUG INTERACTIONS: Thiazide drugs may increase the responsiveness to tubocurarine.

The antihypertensive effects of thiazides may be enhanced in the postsympathectomy patient. Thiazides may decrease arterial responsiveness to norepinephrine. This diminution is not sufficient to preclude effectiveness of the pressor agent for therapeutic use.

PREGNANCY. Pregnancy Category C. Thiazides cross the placental barrier and appear in cord blood. The use of thiazides in pregnancy requires that the anticipated benefit be weighed against possible hazards to the fetus. These hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult.

NURSING MOTHERS. Thiazides appear in human milk. If use of the drug is deemed essential, the patient should stop nursing.

PEDIATRIC USE. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Propranolol hydrochloride (INDERAL®):
Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular. Bradycardia, congestive heart failure, intensification of AV block, hypotension, paresthesia of hands, thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud type.

Central Nervous System. Lightheadedness, mental depression manifested by insomnia, lassitude, weakness, fatigue, reversible mental depression progressing to catatonia, visual disturbances, hallucinations, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Gastrointestinal. Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic. Pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory. Bronchospasm.

Hematologic. Agranulocytosis: nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-Immune. In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous. Alopecia, LE-like reactions, psoriasiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes, and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

Hydrochlorothiazide:
Gastrointestinal. Anorexia, gastric irritation, nausea, vomiting, cramping, diarrhea, constipation; jaundice (intrahepatic cholestatic jaundice), pancreatitis; sialadenitis.

Central Nervous System. Dizziness, vertigo, paresthesias, headache, xanthopsia.

Hematologic. Leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia.

Cardiovascular. Orthostatic hypotension (may be aggravated by alcohol, barbiturates, or narcotics).

Hypersensitivity. Purpura, photosensitivity; rash; urticaria; necrotizing angiitis (vasculitis, cutaneous vasculitis); fever; respiratory distress, including pneumonitis; anaphylactic reactions.

Other. Hyperglycemia, glycosuria, hyperuricemia, muscle spasm; weakness, restlessness, transient blurred vision.

Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy withdrawn.

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CPR: A Survey of Maryland Hospitals

PETER E. DANS MD and KATHERINE L. NEVIN MHS

In some instances CPR can be life-saving; in others it may only prolong the period of dying. Our data suggest considerable institutional variability in management of cardiac arrests. We recommend that more formal mechanisms be adopted by hospitals for CPR management, training, and monitoring of outcome.

The authors are from the Office of Medical Practice Evaluation, The Johns Hopkins Hospital, 550 N. Broadway, Baltimore, Maryland 21205.

In the event of unexpected cardiac arrest, the availability of effective cardiopulmonary resuscitation (CPR) is crucial. Review of CPR management at Johns Hopkins Hospital (JHH) in 1981 led to development of a new method of signaling emergencies, establishment of an adult CPR team, revision of the Do Not Resuscitate (DNR) policy, institution of a formal CPR training program for physicians, and establishment of a routine system for monitoring CPR performance and outcome.[1] To determine whether JHH's need for standardization was unique, we surveyed other hospitals' approaches to CPR management and education. There was widespread variability in how arrests were signaled and who responded.

Methods

Between July and November 1983 each of the 63 member institutions of the Maryland Hospital Association was surveyed to determine: (1) number of cardiac arrests; (2) how cardiac emergencies were signaled; (3) who responded; (4) whether a DNR policy existed; (5) the extent of life-support training offered to physicians, nurses, and other personnel; and (6) whether there was a mechanism for documenting and evaluating CPR attempts and their outcome.

There were 51 acute care, four chronic care, and eight specialty (for example, pediatric or psychiatric) hospitals. Surveys were sent in July 1983 to individuals responsible for CPR management. Forty-three (68 percent) of the questionnaires were completed by nurses in their roles as directors of nursing, staff development coordinators, or critical care unit supervisors. Other respondents included two medical directors, four CPR committee members, and five administrators. Repeated follow-up resulted in completion of all surveys by November 1983. All data were entered on an IBM4341 computer and analyzed according to routine statistical methods.

Results

Signaling Arrests/Who Responds? Methods for signaling cardiac arrest varied. Voice page alone was used in 29 hospitals; a combination of voice and beeper page in 26; voice page and flashing call-board in three; and beeper page alone in two. In one case, a telephone operator tried to contact anyone available in the institution.

Thirty-nine (62 percent) institutions had designated specific respondents from departments, and 31 (50 percent) had at least one special CPR team. None of the four chronic care and three (38 percent) of eight specialty facilities had a formal CPR team (Table 1). Twenty-eight (55 percent) of the 51 acute care hospitals had a team. However, there was no direct correlation between having a team and either beds or annual number of CPRs. Eleven of the 23 hospitals with more than 300 beds had no CPR team (Table 2, next page). This was also true of eight of 21 hospitals reporting more than 150 CPR attempts per year.

Team membership varied from three to nine (median seven). At a minimum, it usually consisted of a critical care nurse, a physician (most often a house officer), and a respiratory therapist. Teams might include an anesthesiologist, EKG technican, a staff nurse, a security officer, and a chaplain. Although physicians predominated as team leaders (81 percent), a nurse often was in charge of arrest management until the physician

Table 1. Institutional Variation in CPR Attempts and Management

Type of Institution	Number	Size Range Number of Beds	Estimated Number of CPR Attempts per Year (Range)	Number with CPR Team
Specialty	8	24–541	0–23	3
Chronic care	4	62–283	20	0
Acute care*	51	40–1078	5–750	28

* Includes community and teaching hospitals.

arrived. Where institutions lacked a defined team, the most qualified physician or nurse on the scene led the resuscitation; problems with assertion of leadership were reported.

Most large institutions had teams for all shifts, but coverage was a problem on weekends and nights in several smaller facilities. Respondents from seven institutions that lacked a team (including JHH) were developing teams. The rest cited low incidence of CPR, small facility size, or cost as deterrents to forming a team.

Do Not Resuscitate Policy Forty-two (67 percent) institutions had a DNR or "No Code" policy. Thirty-one (49 percent) required that any "No Code" order be written by the attending physician. Verbal orders, if accepted at all, required cosignature within 24 hours. Three (5 percent) respondents mentioned that the candidacy of a patient for CPR is routinely discussed on admission; one respondent had a published protocol.[2] Eight respondents noted that involvement of the patient and/or family also must be documented in the medical record. Two institutions indicated that periodic review of the patient's condition must be made or the patient automatically is returned to "full code" status.

Documentation, Evaluation, and Follow-Up of Arrests Although 48 (76 percent) respondents estimated the total number of CPR attempts per year in the institution (Table 2), half were actual figures and the remainder "educated guesses." Thirty-two (52 percent) respondents were able to give a breakdown of arrest distribution (for example, critical care units, emergency room, inpatient units, or outpatient departments).

Estimates of survival were given by only 20 (32 percent) respondents and ranged from 5 percent to 70 percent, (mean 22 percent, median 15 percent, and mode 10 percent). The institution that reported 70 percent predominantly serves referred elective patients, and in the reporting year had 23 CPRs; it had a CPR team and a routine system for managing cardiac emergencies. Another hospital reported only three CPR attempts during the past year; two patients survived. The 5 percent estimate was given for a community hospital.

Estimates of how often CPR was performed on patients who died in the hospital were given by 17 (27 percent). Their figures ranged from 1 percent to 100 percent, with a mean of 55 percent and mode and median of 50 percent. The two 100 percent values were reported by hospitals with very low death rates, and the 1 percent estimate was for a facility where most patients are considered to be terminally ill.

Forty-three institutions (68 percent) reported having a special administrative unit. In 31 this consisted of multidisciplinary CPR committees or subcommittees that periodically reviewed all resuscitation efforts. Where no formal committee existed, reviews were performed by quality assurance office personnel, nurse supervisors, or directors of coronary care units. Thirty-three respondents (52 percent) reported a policy of routine observation and evaluation of CPR events, usually by a nurse supervisor or staff nurse. The existence of an arrest evaluation form was noted by a few respondents.

CPR Education In 50 (81 percent) hospitals, certification in Basic Cardiac Life Support (BCLS) was mandatory for all nursing personnel. The Advanced Cardiac Life Support (ACLS) program was offered to nurses in emergency and critical care areas in nine hospitals. CPR training for physicians was mandatory in 19 hospitals (30 percent); seven institutions reported that BCLS training was required only for physicians in Emergency Medicine and/or Cardiology. Three respondents volunteered that there was a general lack of

Table 2. Relationship of Teams to Hospital Size and CPR Attempts per Year

Estimated Number of CPR Attempts	Hospital Size							
	≤150 Beds (n = 17)		151–300 Beds (n = 23)		301–450 Beds (n = 13)		≥450 Beds (n = 10)	
	With CPR Team	Without CPR Team	With CPR Team	Without CPR Team	With CPR Team	Without CPR Team	With CPR Team	Without CPR Team
5–50	5 (2)*	7 (5)*	1	2 (1)*	0	1*	1*	0
51–150	1	2	3	2	2	1	0	0
151–250	0	1	6	2	2	1	0	1
>250	0	0	0	0	1	0	3	3
Unknown (15)	1	0	3	4 (2)*	1	4	1	1
Total number hospitals in each sample	7	10	13	10	6	7	5	5

* Chronic care or specialty hospitals.

interest among their staff physicians in becoming certified in CPR.

Discussion

The data suggest considerable institutional variability in management of cardiac arrests. In fact, seven respondents volunteered that their system of handling cardiac emergencies could be improved and cited assumption of leadership and crowd control as specific problems. Although 43 (68 percent) respondents had special administrative units to review CPRs only 24 (38 percent) could provide actual figures for the number of arrests, and only 20 (32 percent) could provide an estimate of the patient survival to discharge. Fewer than one-third of respondents could estimate the percentage of patients who die in hospital and on whom CPR is attempted.

The survey revealed a lack of uniformity in DNR policies and their implementation, as well as in the approach to CPR education. Most hospitals had mandatory BCLS training programs, and some even offered ACLS training to nurses, but only 30 percent required staff physicians to be certified in basic life support.

Given that institutions differ widely in size, patient populations, and staff composition, variation in CPR management is to be expected. However, in only one small specialty institution was CPR not carried out in the previous year. Furthermore, even the 24 (38 percent) hospitals reporting over 100 CPR attempts varied widely in approach to CPR management.

Conclusion

CPR should not be left to chance. Hospitals should have a formal CPR plan that includes attention to (1) signaling of emergencies, (2) deployment of equipment and personnel, (3) training of physicians and nurses likely to respond to arrests as well as other personnel (such as laboratory technicians or admitting clerks) in areas where arrests are more likely to occur, (4) routine monitoring of the quality of arrest management, (5) regular statistical reports to the medical and nursing staff on patients resuscitated and their outcome, and (6) formulation and promulgation of a "Do Not Resuscitate" policy. A specific institutional locus of responsibility should be defined to assure that this plan is carried out and monitored. Only when such a program is established can we reasonably assure the ability to provide high quality life support regardless of where patients are admitted.

References

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Medicolegal Hotline

for any emergency

November	*Victoria E. Selph, Esq.*	*301-868-8950*
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Cardiac Arrest: It Happened to Me

RAYMOND L. CLEMMENS MD

Jim Fixx, famous author and runner, had a heart attack, cardiac arrest, and died suddenly while jogging at age 52. The same thing happened to me, except that I survived. I was resuscitated by skillful fire department paramedics and was transferred to the coronary care unit at Saint Joseph Hospital. I had been without a heartbeat for thirty minutes.

Dr. Clemmens is Professor of Pediatrics, University of Maryland School of Medicine.

On April 20, 1984, the temperature was about 50 degrees and there wasn't a cloud in the sky. It was a great morning to be jogging. I was within a few yards of finishing my customary, early morning, eight-mile run. Without warning I had a heart attack and cardiac arrest. When I was found, there was no pulse or respiration.

Two elderly women were first to walk by. They flagged down the first car that came along, driven by a young landscape architect on his way to work. His name was Tom Stone, and he was a volunteer fireman trained in cardiopulmonary resuscitation. He asked a neighbor to call the emergency 911 phone number. The fire department received the phone call at 8:37 a.m.

Stone did a quick evaluation. It was obvious I was not breathing. Not so obvious was the fact that my heart was not beating. He checked for a pulse and found none. There was no evidence of heartbeat. I was in a state of full cardiac arrest. He made certain there was nothing in my mouth and no obstruction to my breathing passages. He then positioned my head and neck in the recommended manner and blew into my mouth.

Bystanders and neighbors gathered around. One walked up the street to my home and summoned my wife and son. Meanwhile, Stone had begun CPR. He gave two quick breaths into my mouth, then five firm compressions of his hands on the chest over my heart and repeated the process.

County Fire Department

The Baltimore County fire department arrived on the scene, one mile from the fire station, two minutes after they received the initial phone call at 8:39 a.m. The fire department was well-prepared with an ambulance, a fire engine, and a special van that carried equipment necessary for such an emergency. There were three paramedics: Herbert Taylor, Harold Cohen, and William Carter; four other men on the fire truck were there as backup personnel.

Stone stepped aside, and the paramedics took over. With scissors they removed a sweatshirt, the only clothing I had on above the waist. They administered CPR manually as the mechanical equipment (thumper) was prepared. One paramedic compressed my chest over the heart. The other inserted the esophageal obturator airway and attached it to the oxygen supply. Another paramedic inserted a needle into a vein on the back of my wrist so that intravenous medications could be given. At that point, all systems were prepared and mechanical CPR was begun with the thumper. There was still no pulse or respiration. The first countershock was given with the defibrillator at 8:40 a.m. The first sign of a useful heartbeat was noted at 9 a.m. Five electrical jolts with the defibrillator had been administered. The paramedics had been working for exactly 21 minutes when my heart began to beat again.

The ambulance crew placed me on a stretcher and lifted me to the rear of the ambulance. The time was 9:17 a.m. I was still receiving oxygen by a positive pressure respirator. We arrived at St. Joseph Hospital emergency room at 9:21 a.m. I remained unconscious and was unable to breathe without a mechanical respirator. The kind and degree of damage (especially to the nervous system) sustained from oxygen deprivation remained to be determined.

Hospitalization

I have absolutely no memory of the first seven days of hospitalization; it was a classical case of amnesia resulting from cerebral anoxia.

I remained in the emergency room for just a little over an hour. At that time I came under the care of Richard Biggs MD, a cardiologist, who was to be my attending physician. In the emergency room and the coronary care unit there followed a seemingly endless series of procedures, investigations, consultations, and treatments. Some investigations performed included brain wave tests, electrocardiograms, brain scans, blood gas determinations, other blood chemistries, x-rays, and urine studies. Because questions remained about my overall status, Dr. Biggs requested consultations from other specialists including a neurologist, urologist, pulmonologist, and later, a speech and language consultant.

One of the more notable procedures Dr. Biggs performed was installation of a catheter into the chambers of my heart. The Swan-Ganz Catheter was inserted in one of the major blood vessels in my neck until it reached the heart where it was fixed in place. This made possible the determination of different characteristics of the blood and thus provided close monitoring of my status.

I was transferred to the coronary care unit at about 10:30 a.m. with four different tubes attached to my body: the Swan-Ganz Catheter; a Foley Catheter (this was necessary because urinary output had diminished and kidney damage from anoxia was a possibility); the intravenous tube that the paramedics had installed (which was still being used for intravenous fluids and medication); and the airway through which I received ventilatory assistance and oxygen. I was beginning to breathe on my own; the respirator worked in tandem with my breathing efforts and served as a back-up system. My ability to breathe improved slowly but continuously.

I think of the afternoon of April 21 as being the turning point of my clinical course and the beginning of my perceptive improvement. I had been in the hospital about 27 hours. Three important things happened: I regained consciousness; they removed the airway from my throat and freed me from the respirator; and I spoke for the first time, saying "Hello, Mama" to my wife.

During the first few days of hospitalization, drug therapy was aggressive and intense. The first concerns centered on the nervous system and my brain, which had sustained oxygen deprivation. To counteract the brain swelling that follows the anoxia my nervous system had experienced, I was given massive doses of Medrol (an adrenocortical steroid medication). When my arms and legs demonstrated repetitive convulsive movements suggestive of early seizures, I received large doses of Dilantin.

The attending physician wrote in his progress notes: "The patient's initial course was rather hectic with cardiac rhythm disturbances requiring Lidocaine and eventually Bretylium." Other drugs given were Lopressor, nitroglycerine, and Lasix.

The Foley Catheter was removed on the third hospital day, and the final two tubes were removed on the fifth and sixth hospital days. I began to take liquids by mouth on the third hospital day and was permitted to have a diet of semisolid foods on the fifth day. I was allowed to get out of bed for brief periods beginning the sixth day, and was transferred from the coronary care unit to a regular hospital room on the sixth hospital day.

Recovery

My improvement after the third hospital day was progressive but not without periods of real anxiety. After the first several days, it was obvious that I had sustained significant impairment to my intellectual, cognitive, and personality functions.

When I first regained consciousness, I knew my wife right away. However, I did not know the names of my children and did not recognize my grandchildren. I could not read or write. I was unable to identify a watch, a ring, or a necktie. The language consultant who examined me noted that I was unable to carry out a simple command and was unable to name three animals.

These changes aroused considerable anxiety among my family. They had no idea what to expect and what the implications were for my future. When the doctors were asked the prognosis, they told my family there was no way to be sure; they would have to wait and hope for the best.

The memory loss was quite striking and bothered me considerably. It was difficult to identify any pattern to the memory loss. For example, I was able to remember some friends and activities of early childhood, but I didn't know my next door neighbor, the names of people I worked with, or the name of our Department Chairman.

I still remember nothing of the first seven days after the heart attack. There are little islands of the past that I don't remember; other things, seemingly of less importance, I do remember. For example, I conducted an out-of-town pediatric clinic for the health department on April 6, 1984. I have absolutely no memory of anything that happened to me that day. I don't remember making the trip or seeing the patients. But the clinic charts I dictated that day are in the record to prove I was there.

Gradually my cognitive deficits have diminished, and my memory problems have subsided. I still have subtle memory problems. My handwriting is perhaps less legible. Otherwise, my faculties and capacities have recovered; if not complete, the recovery at least has been encouraging.

As the end of my second week in the hospital approached, improvement in my neurological status gradually accelerated. My cardiac status also had progressed well. The family began to relax and have a tremendous feeling of appreciation, relief, and euphoria. From there onward, the changes were all positive.

My ability to read and write slowly returned, as did my other cognitive process over a period of several weeks. Most faculties that had been compromised gradually returned. Memory loss was slowest in improvement, and my memory is still weaker than I would like it to be. It continues to improve gradually.

Because of the severity and unusual nature of my neurological deficits, there was some uncertainty about my readiness to return to work. The cardiologist had no misgivings about my cardiac status. Higher intellectual and language skills were difficult to measure. The central question concerned my readiness to practice medicine and to accept responsibility for patient care.

There was no test available for that.

It was mutually agreed that a trial period under the direction of another physician acting as preceptor would be appropriate. Thus, I was able to examine patients and do other clinical work while another physician closely checked my performance. It was like being a third-year medical student again, but it worked well. I was soon "certified" and authorized to assume independent medical responsibilities.

Benefits of Strenuous Exercise

I had never had any signs or symptoms of heart trouble. I had numerous electrocardiograms in the past and all were normal. I exercised regularly and vigorously. I have completed five full marathons of 26.2 miles each. (My best time was just barely under five hours, but I believe that to finish is to win). I religiously ran eight miles every other day and walked eight miles a day in between. I controlled my weight and watched my diet and blood pressure. My blood cholesterol levels always had been normal. I had no family history of heart disease. There was no reason for me to have any major concern about a heart attack.

I am constantly mindful of the fact that I am fortunate to be alive. The probability I will experience another heart attack in the future is considerable. I am more cautious now, and I try to follow the customary recommendations for heart disease prevention.

How safe is strenuous physical exercise? Vigorous jogging is not foolproof protection against heart disease. My experience, and that of Jim Fixx, gives testimony to that fact. There is no doubt in my mind that my heart attack was directly related to the fact that I was running. The most recent studies have convincingly demonstrated that there is some increase in the probability of heart attack during strenuous exercise. The same studies have documented the fact that, over the long haul, the health benefits of strenuous exercise far outweigh any associated dangers. Other studies have demonstrated that the greater the level of habitual activity, the lower the risk during exercise and the greater the overall benefit.

I remain a firm believer in the value of physical exercise. I try to walk six miles every day. I believe that my chances of surviving would have been markedly diminished had it not been for the benefits of jogging.

Friday, April 20, 1984
Chronology of Events

A.M.	
8:30	Time of collapse
8:34	CPR (manual) by Tom Stone
8:37	Phone call to fire department
8:39	Paramedics arrive at scene
8:39	Mechanical CPR begins
8:40	First countershock given
9:00	Fifth countershock. Pulse returns
9:17	Ambulance leaves site with patient
9:21	Ambulance arrives St. Joseph Hospital's Emergency Room
10:30	Patient transferred to Coronary Care Unit

Time that patient had no heartbeat	30 minutes ±
Time till consciousness regained	27 hours
Time in Coronary Care Unit	5 days
Total days in hospital	15 days

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Congenital Cardiovascular Malformations in the Baltimore-Washington Area

JUDITH D. RUBIN MD, CHARLOTTE FERENCZ MD, ROBERT J. McCARTER ScD, P. DAVID WILSON PhD, JOANN A. BOUGHMAN PhD, JOEL I. BRENNER MD, CATHERINE A. NEILL MD, LOWELL W. PERRY MD, SEYMOUR I. HEPNER MD, and JOHN W. DOWNING

The Baltimore-Washington Infant Study (BWIS) provides an extensive data source for elucidation of the etiologic factors for congenital cardiovascular malformations (CCVM). Preliminary analysis yielded information on prevalence of CCVM at live birth[1] and on possible associations between CCVM and hereditary blood disorders[2] and maternal mitral valve prolapse.[3] Not a single disorder, CCVM is a group of abnormalities composed of lesions of variable types and severity and with heterogeneous etiologies. A very large study population is needed before analysis by different types of cardiac lesions can provide information on specific etiologic risk factors.

Rubin is Assistant Professor, Ferencz is Professor, McCarter is Assistant Professor, and Wilson is Assistant Professor in the Department of Epidemiology and Preventive Medicine. Boughman is Associate Professor, Division of Genetics, Department of Obstetrics and Gynecology, University of Maryland School of Medicine. Brenner is Assistant Professor, Neill is Associate Professor, Perry is Professor, Hepner is Assistant Professor, and Downing is Professor in the Divisions of Pediatric Cardiology at the University of Maryland, the Johns Hopkins University, Children's Hospital National Medical Center, Georgetown and Howard Universities. Supported by National Heart, Lung and Blood Institute Grant #HL 25629.

Correspondence: Judith D. Rubin MD, University of Maryland School of Medicine, Dept. of Epidemiology and Preventive Medicine, Room 13-015 Bressler Research Bldg, 655 W. Baltimore St., Baltimore, MD 21201.

CCVM make up a major segment of clinically significant birth defects; they are associated with high mortality and morbidity, costly care, and lifelong risks of medical and social problems. The BWIS is an ongoing regional case-control study aiming to identify genetic and environmental risk factors for CCVM by comparison of data on over 2,000 cases and 2,500 controls to be enrolled over the six years 1981 to 1987. This report, based on 1,057 cases and 1,388 controls from the first three years of the study, describes the distribution of CCVM in the Baltimore-Washington area and the regional collaborations that have made this investigation possible.

Essential elements of the study design are:

- Definition of a geographic area, the resident birth cohort of which forms the target population of the investigation
- Identification of all CCVM cases among resident live births using multiple ascertainment sources
- Selection of a random sample of the birth cohort to serve as controls
- Collection of detailed demographic, biologic, and environmental data
- Data analysis searching for individual risk factors and for multifactorial associations of specific factors and of categories of potentially damaging exposures

Methods

The study area consists of Maryland, the District of Columbia, and five adjacent counties of northern Virginia. Through the regional neonatal programs and crippled children's services, infants with heart disease are referred to one of these centers: University of Maryland Medical System, Johns Hopkins University Hospital, Children's Hospital National Medical Center, Georgetown University Hospital, and Howard University Hospital. Cases and controls are resident infants born alive in civilian hospitals.

The major sources of case ascertainment are cardiologists at the five pediatric cardiology centers. Cases of CCVM are infants with diagnoses of structural cardiac abnormalities confirmed before one year of age by echocardiography, cardiac catheterization, surgery, or autopsy. The sole exclusion is isolated patent ductus arteriosus in premature infants (gestational age less than 38 weeks). Each case is assigned a precise cardiac diagnosis, and associated major noncardiac malformations are coded by organ systems. Specific codes identify chromosomal and other genetic abnormalities and malformation syndromes; heritable disorders are identified by McKusick codes.[4]

A small number of CCVM cases may be missed by this registration process. For example, severe heart disease may be recognized only at autopsy (when infant death occurs soon after birth) or may be diagnosed clinically, but the infant may die before transfer to a cardiology center. The search for these missed cases consists of systematic reviews of autopsy logbooks at pathology departments of the participating hospitals and annual reviews of death certificates.

Control infants are chosen as a random sample of the birth cohort from which the cases arise. For each year, a computer program selects an annual random sample of 500 births from area hospitals, allocating to each hospital the proportion that the institution contributes to the resident births. Control infants are distributed within hospitals by birth month and "index month" (equivalent to month of diagnosis for cases) so that in

the total control sample the age distribution at interview will be similar for cases and controls. Additional infants are randomly selected as potential replacements. Permission to contact the family is obtained from the physician attending the birth.

Participation by hospitals and physicians has been excellent. Fifty-three area hospitals with obstetrical services were invited to cooperate with control selection and hospital record review; the 52 participating hospitals are listed in Table 1. Over 700 physicians have agreed to have their patients contacted for permission to complete the study interview.

The major data-gathering instrument is a comprehensive questionnaire detailing sociodemographic and medical information as well as environmental exposure data. Field interviewers who administer the questionnaire received special training in communication with parents of seriously ill and deceased infants. In addition, consultants in occupational toxicology conducted training sessions with the interviewers on techniques of obtaining occupational and home exposure information.

Identification of etiologic factors will be the objective of complex analytic procedures performed on the final data. In this article we report preliminary descriptive data on cases and controls whose families completed interviews during the first half of the study (1981 to 1984).

Results

In the first three years of the study 1,128 cases were ascertained: 1,112 through the pediatric cardiology cen-

Table 1. Hospitals Participating in the Baltimore-Washington Infant Study

Baltimore City

Francis Scott Key Medical Center
Franklin Square Hospital
Greater Baltimore Medical Center
Johns Hopkins Hospital
Maryland General Hospital
Mercy Hospital
Provident Hospital
Saint Agnes Hospital
Saint Joseph Hospital
Sinai Hospital
South Baltimore General Hospital
Union Memorial Hospital
University of Maryland Medical System

Western Maryland

Cumberland Memorial Hospital
Frederick Memorial Hospital
Garrett County Memorial Hospital
Sacred Heart Hospital
Washington County Hospital Association

District of Columbia

District of Columbia General Hospital
Georgetown University Hospital
George Washington University Hospital
Greater Southeast Community Hospital
Howard University Hospital
Providence Hospital
Sibley Memorial Hospital
Washington Hospital Center

Central Maryland

Anne Arundel General Hospital
Carroll County General Hospital
Harford Memorial Hospital
Howard County General Hospital

Eastern Maryland

Dorchester General Hospital
Edward W. McCready Memorial Hospital
Kent and Queen Anne's Hospital
Peninsula General Hospital
Memorial Hospital at Easton
Union Hospital of Cecil County

Southern Maryland

Calvert Memorial Hospital
Physicians Memorial Hospital
Saint Mary's Hospital
Southern Maryland Hospital Center

Capital Area

Holy Cross Hospital of Silver Spring
Montgomery General Hospital
Prince George's General Hospital and Medical Center
Shady Grove Adventist Hospital
Washington Adventist Hospital

Northern Virginia

Alexandria Hospital
Arlington Hospital
Fairfax Hospital
Fauquier Hospital
Loudoun Memorial Hospital
Potomac Hospital
Prince William Hospital

ters and 16 through review of hospital and vital records. The primary cardiac diagnoses of interviewed cases, including the 16 "community search cases" representing 1.4 percent of the total interviewed case population, are shown in Table 2.

Prompt referral of distressed newborns appears to be the rule in the study area. Figure 1 shows the age at diagnosis of CCVM for cases with severe lesions (looping abnormalities, conotruncal malformations, major septation defects, atresias, and hypoplasias) and mild lesions (stenoses and other valve lesions, septal defects, and patent ductus arteriosus).

Interviews have been completed with the families of 1,057 cases. Reasons for noninterview of cases are shown in Table 3.

Interviews have also been completed with the families of 1,388 controls. To achieve this target number of control interviews, a total of 1,697 control selections were needed. Reasons for replacement of first-choice controls are shown in Table 4.

Mothers of the study infants (97.1 percent and 99.1 percent of cases and controls, respectively) were the primary respondents, supported by one or more additional people in 298 (28.2 percent) case interviews and in 302 (21.8 percent) control interviews. Fathers of cases participated in 19.8 percent of interviews and fathers of controls in 15.7 percent.

Most interviews were conducted at the respondents' homes (90.8 percent and 92.5 percent of case and control interviews, respectively). Others were conducted at workplaces, hospitals, and homes of friends or relatives. Fewer than 1 percent of interviews were carried out by mail or by telephone.

Table 2. Diagnoses of Interviewed Cases

Ventricular septal defect	270 (2)*
Atrial septal defect	91
Endocardial cushion defect	90
Coarctation of aorta/interrupted aortic arch	81 (1)
Tetralogy of Fallot	77 (1)
Pulmonic stenosis	77
Hypoplastic left heart syndrome	58 (2)
Transposition of the great vessels	48 (5)
Other conotruncal defects	45 (2)
Looping abnormalities	34
Aortic stenosis	33
Other valve and vessel anomalies	29
Patent ductus arteriosus	28
Total anomalous pulmonary venous return	17
Pulmonary atresia	17
Epstein's anomaly	17 (3)
Tricuspid atresia	16
Miscellaneous	29
Total	1,057 (16)

* Parentheses denote community search cases

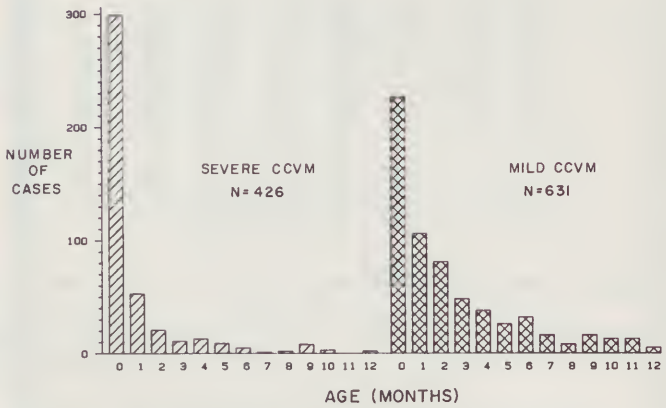


Figure 1. Age at diagnosis by severity of cardiac lesion.

Table 3. Case Interview Rates

	Number	Percent
Interview completed	1,057	93.7
Not interviewed		
Medicolegal problem	6	0.5
Adoption	2	0.2
Unable to locate	17	1.5
Language problem	2	0.2
Parent refusal	44	3.9
Total cases ascertained	1,128	

Table 4. Reasons for Control Replacement

	Number	Percent
Physician refusal	54	3.2
Unable to locate	111	6.5
Language problem	13	0.8
Parent refusal	131	7.7
Interview completed	1,388	
Total control selections	1,697	

Table 5. Regional Distribution of Births, Cases, and Controls

	Births (percent)	Cases (percent)	Controls (percent)
Central Maryland*	35.31	38.79	40.20
Western Maryland†	5.09	5.30	6.20
Eastern Maryland‡	4.54	4.45	5.40
Southern Maryland§	3.28	3.88	2.67
Capital Area‖	20.73	22.33	18.66
District of Columbia	10.28	9.56	8.79
Northern Virginia#	20.76	15.70	18.08

* Baltimore City, Anne Arundel, Baltimore, Carroll, Harford, and Howard Counties
† Allegany, Frederick, Garrett, and Washington Counties
‡ Caroline, Cecil, Dorchester, Kent, Queen Anne's, Somerset, Talbot, Wicomico, and Worchester Counties
§ Calvert, Charles, and St. Mary's Counties
‖ Montgomery and Prince George's Counties
Fairfax, Fauquier, Loudoun, Prince William, and Stafford Counties, and the Cities of Alexandria, Arlington, Fairfax, Falls Church, Manassas, and Manassas Park

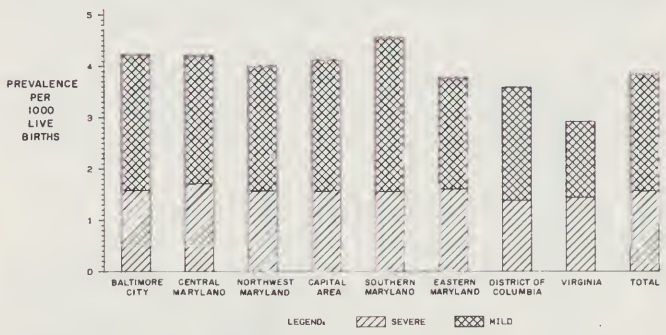


Figure 2. Regional prevalence by severity of cardiac lesion.

Table 5 shows the regional distribution of cases and controls in the BWIS in relation to the proportional distribution of live births in the study area.

Regional prevalence of CCVM cases for the first three years of the study is shown in Figure 2. Prevalence rates for severe CCVM were similar throughout the region; there was a lower rate of mild heart disease among cases referred from northern Virginia.

Selected characteristics of the study subjects are shown in Table 6. Cases and controls are similar with regard to race, sex, plurality, and birth order. Four percent of the control group had major noncardiac malformations, while over one-fourth of the cases had genetic, infectious, toxic, or other defects in association with cardiac malformations.

Discussion

Approximately 96 percent of severe CCVM cases within the target population were registered through the pediatric cardiology centers where diagnostic confirmation was achieved. While it is more difficult to estimate the degree of ascertainment for milder lesions, a lower rate is likely, primarily as a result of nonreferral of asymptomatic patients to cardiology centers. There

Table 6. Characteristics of Study Subjects

		Cases (n = 1,057)		Controls (n = 1,388)	
		Number	Percent	Number	Percent
Sex	Male	523	49.5	706	50.9
	Female	534	50.5	682	49.1
Race	White	719	68	919	66.2
	Nonwhite	338	32	469	33.8
Plurality	Single	1,032	97.6	1,369	98.6
	Twin	23	2.2	19	1.4
	Triplet	2	.2	—	
Birth order	1	343	32.5	474	34.2
	2	304	28.8	428	30.9
	3	210	19.9	277	20
	4+	199	18.8	207	14.9
	Unknown	1		2	
Noncardiac malformations	None	765	72.4	1,340	96.5
	Chromosomal	131	12.4	2	.1
	Mendelian	56	5.3	9	.6
	Infectious	4	.4	–	
	Toxic	2	.2	–	
	Possible syndromes	10	.9	–	
	Miscellaneous	89	8.4	37	2.7
Vital status	Alive	882	83.4	1,380	99.6
	Dead	175	16.6	5	.4
	Unknown	—		3	

was surprisingly little variation in the prevalence of mild CCVM between urban and rural areas, a finding that reflects the wide regional availability of cardiac consultation to community physicians.

Random control selection has achieved a population of infants without CCVM that is representative of the area live births. There is slight underrepresentation of the District of Columbia metropolitan area, including Montgomery and Prince George's counties and Northern Virginia, due to nonparticipation by a District of Columbia hospital where almost 5 percent of area births occur.

Establishment of a community laboratory has been useful in etiologic studies of other chronic diseases.[5] Information on residents of a defined geographic area allows meaningful inferences regarding a population group, since distinguishing attributes of affected and nonaffected persons may identify differences related to the risk of the disease itself. Because controls are used to estimate rate of exposure to risk factors in the unaffected population, it will be possible to estimate CCVM incidence in exposed and nonexposed groups and therefore the relative risk of CCVM among the exposed. The controls provide a reference population in which a background level of exposure can be determined and against which the exposure rates among cases can be compared.

Acknowledgments

The authors extend their appreciation to the medical staffs and record room personnel of the collaborating hospitals throughout the region; to Drs. Genevieve Matanoski, Charles Billings, and Peter Hamill, consultants in Toxicology, Occupational and Environmental Medicine; to Glenn Heartwell, study coordinator; to Linda Finazzo, Valerie Griffin, Rose Marie Cherry, and Crystal Stroud, case registrars; to Michelle Wade, control registrar; to Alice Good, field supervisor; to Jeanne Schlossberg, Gertrude Rosen, and Kathleen Sadler, interviewers; to Betty Williams, data editor, to Teena Maultsby and Beverly Law, study secretaries; and to the Maryland Center for Health Statistics, Department of Health and Mental Hygiene, State of Maryland; the Center for Health Statistics, Virginia State Department of Health, Commonwealth of Virginia; and Statistics and Vital Research Division, Department of Human Services, Government of the District of Columbia.

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The Many Faces of Apical Hypertrophic Cardiomyopathy

FRANK W. DAVIS, Jr., MD

In recent years there has been considerable interest in a form of hypertrophic cardiomyopathy that clearly differs from the commonly recognized asymmetrical septal hypertrophy and from concentric hypertrophy. In this subset of hypertrophic disease the predominant change is apical in location. Yamagushi *et al.*[1] have described this syndrome, emphasizing "giant negative T waves."

The author is at the Johns Hopkins University School of Medicine and Cardiovascular Division, Johns Hopkins Hospital, Baltimore, Maryland.

A 55-year-old white male (first seen in 1971 at age 41) was referred for cardiac evaluation of findings noted during naval retirement proceedings. Both his parents had heart disease: his father suffered an infarct at age 60; his mother died of some form of heart disease at age 35. He denied all cardiac symptoms. During the naval retirement examination he was found to have an abnormal ECG, a heart murmur, and hyperlipidemia.

On physical examination in 1971 his BP was 120/90; his cardiac examination showed a modestly accentuated M-1 and a grade I presystolic rumble at the apex. There was a prominent S-4 gallop. ECG showed nonspecific T-wave changes without evidence of hypertrophy but with left atrial abnormality. A double 2-step test elicited global ST segment depression. Chest x-ray was normal. Lipid profile was consistent with Type II hyperlipoproteinemia.

Annual follow-up since 1971 has continued to demonstrate the same auscultatory abnormalities. In 1976 slight increase in left ventricular size was first detected in chest x-ray (16/32). M-mode echocardiogram in 1976 showed anterior mitral leaflet notching, thought then to suggest elevated left ventricular end diastolic pressure (LVEDP). Poor posterior leaflet motion was noted. Minor noncardiac symptoms occurred episodically, but he continued an active life, regular physical exercise, and full-time employment as an engineer.

In 1984 a treadmill stress test was performed at the request of an insurance company. Using a modified Bruce protocol, the procedure was interrupted at 8 minutes with global ST segment depression occurring, the maximal change being 3 mm depression in lead V-6. This finding led to diagnostic cardiac catheterization. Coronary arteries were large and without lesions, but left ventriculogram showed striking apical hypertrophy. This was accompanied by systolic cavity obliteration. No aortic or mitral gradient was noted. Left ventricular pressures before contrast were 126/10–20, after contrast 125/10–33. End diastolic volume was 85 and systolic volume 20, the ejection fraction 75 percent. Two-dimensional echocardiogram and repeat M-mode study demonstrated the classical findings of apical hypertrophic cardiomyopathy.

Discussion

Patients previously described with this syndrome have sometimes presented a history of chest pain[2,3]; at least one patient[2] had "inferior ischemic changes" with graded exercise testing. Systolic murmurs have been noted in the minority of patients.[2,3]

The many faces demonstrated by this case differ in some respects from others reported with this abnormality. The murmur in late diastole was noted by the examining physician in 1971 at Bethesda Naval Hospital and noted annually on routine follow-up through 1984. This adds another disorder to the group of disorders known to mimic mitral stenosis.[4]

The global ST segment depression with exercise noted first in 1971, and again with conventional treadmill testing in 1984, exceeded the reported ST changes and actually led to the cardiac catheterization. The diagnosis of apical hypertrophic cardiomyopathy was

immediately apparent (Figure 1) and supported by M-mode (Figure 2) and two-dimensional echocardiography.

The giant T-wave inversion originally noted in the disorder was not noted, but this finding is not present in the majority of a recent series of 23 patients.[3] The left atrial abnormality in the present ECG lent further support to the original concept of mitral stenosis, obviously not present at catheterization.

This case is presented to emphasize the importance of the newly described variant of hypertrophic cardiomyopathy as an entity capable of mimicking not only ischemic heart disease but also valvular heart disease, both mitral stenosis (present patient) and mitral regurgitation.[3] Two-dimensional echocardiography should establish the diagnosis and eliminate the need for invasive studies in patients with chest pain, ECG abnormalities, and positive treadmill studies.

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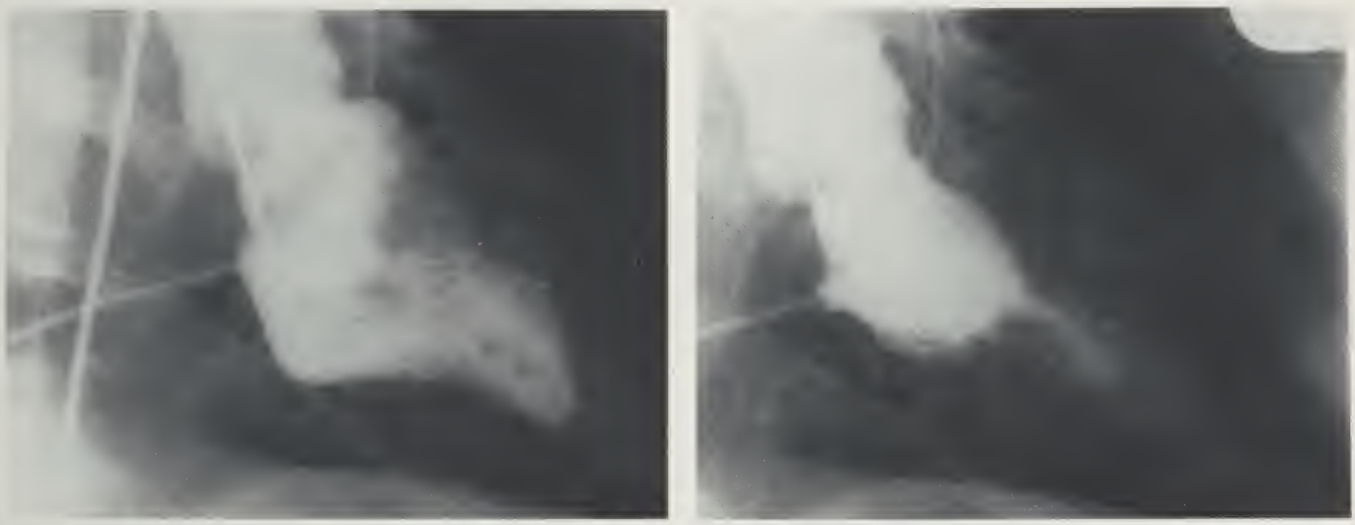


Figure 1. Left ventriculogram (a) end-diastole (b) end-systole. Note the "ace of spades" appearance.

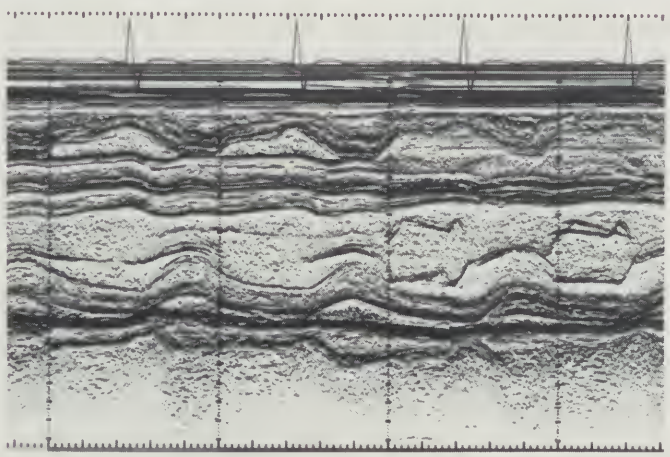


Figure 2. M-mode echocardiogram displaying increasing septal and free wall thickness toward the apex and small apical systolic cavity size.

Medical Miscellany

The AMA MAP Service

The American Medical Association has announced a new activity that will be of interest to any physician interested in developing or modifying a medical practice. The AMA Market Area Profile (MAP) Service, created as part of the Association's Competition Action Plan, is designed to assist physicians in establishing and maintaining a successful medical practice by providing them with detailed demographic and health resource data on an existing or planned practice site.

The MAP Service offers physicians individualized, computer-generated data profiles on any area in the U.S. Each Market Area Profile consists of six data reports:

- *Area Profile Report* 1980 census data (population, age, sex, housing, occupation, income, etc.) for the area the physician has selected.
- *State Area Profile Report* 1980 census data for the state in which the physician-selected area is located, provided for comparison purposes.
- *Demographic Trends Report* 1980, current year, and five-year projected population and demographic data (population, age, sex, household size, etc.).
- *State Demographic Trends Report* A trends report for the state in which the selected area is located, provided for comparison purposes.
- *Physician Report* Statistical information on the number of physicians in the area, by medical specialty, age, and major professional activity.
- *Hospital Report* Detailed information on hospitals in the selected area, including: number of beds; admissions, utilization, and census figures; facilities and services; and a profile of the medical staff. (If there are more than four hospitals in the selected area, a summary listing of the hospitals is provided instead.)

The information provided in a MAP profile can be beneficial to all physicians, no matter what their practice situation. New physicians will find it helpful in practice site-selection decisions, whether they are investigating specific practice opportunities or comparing several practice sites. Established physicians can use the profiles to make decisions about expanding, relocating, or modifying an existing practice. For example, a physician might wish to use the MAP demographic reports to compare his/her current patient base with the potential patient population of the community. Another physician might want to study the five-year projected population figures as part of the development of a long-range practice plan. In any event, the Market Area Profile Service is a valuable planning tool that can help any physician make the right decisions about a medical practice.

A key feature of the MAP Service is the flexibility offered physician subscriber in selecting the area to be profiled. There are four choices: (1) County, (2) ZIP Code, (3) City/Town, or (4) Ring Study. The Ring Study option is a unique aspect of the MAP Service that allows the physician to define precisely the area of study in relation to an existing or planned office site. Using a specific street intersection as the center point, the physician can define the area as a ring *of any size* (for example, 5 or 10 miles) around that intersection. This is extremely useful in instances where a standard geographic description does not adequately describe a physician's service area.

The cost of the Market Area Profile Service ranges from $95 to $195, with substantial discounts for AMA members, medical students, and residents. Along with the six profile reports, physicians receive a User's Manual that provides data source information and offers advice on how to interpret and apply the data to a practice situation.

For further information and to receive the MAP Registration Package, contact the AMA Market Area Profile Service, American Medical Association, 535 North Dearborn, Chicago, IL 60610 (312-645-4719).

• • •

The Wendell Muncie Annual Prize Award

The Maryland Association of Private Practicing Psychiatrists and the Maryland Psychiatric Society jointly announce a contest for the awarding of a $300 prize to the author who submits the best paper pertaining to a psychiatric subject.

Eligible are physicians who reside or practice within the bounds of the Maryland District Branch of the American Psychiatric Association who, as of the deadline for the submission of the paper, are no more than ten years beyond graduation from medical school, have completed at least one year of an approved psychiatric residency, and are currently active in the profession of psychiatry.

The subject may be a clinical, research, theoretical, or other aspects of any topic pertaining to psychiatry or allied fields. The paper must be unpublished, and there are no restrictions on length.

The winner will be asked to read his or her paper at the joint meeting of the two societies scheduled for April 17, 1986.

All manuscripts must be received by January 15, 1986. They should be mailed to Michael J. Richardson MD, Committee Chairperson, The Wendell Muncie Annual Prize Award, 1204 Maryland Ave., Baltimore, MD 21201.

• • •

The Open Forum

Epilepsy Awareness Month

November is National Epilepsy Awareness Month and locally the Epilepsy Association of Maryland (EAM) is gearing up to increase public understanding of the condition that affects more than 40,000 Marylanders. Special attention is being devoted this year to eliminating the stigma that children with epilepsy face. Of the approximately 100,000 new cases diagnosed nationally each year, 75 percent occur in those under 18.

EAM strives to help people with epilepsy lead normal lives by addressing a variety of needs that arise as a result of society's unwillingness to accept people with epilepsy. Information and referral, individual and family counseling, support groups, and pre-employment training are some of the initial reasons people come to EAM. Employment evaluation, job development, and employer referral are often used by those having vocational difficulty. Clients desiring to learn independent living skills, away from the sheltered family or institutional setting, are referred to EAM's Residential Services Program in which 12 scattered sites in the community serve as "home."

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On Physicians' Dispensing Drugs

To the Editor:

The Maryland Pharmaceutical Association is the statewide professional society of pharmacists. Recently we became aware that a mailing has been made to Maryland physicians by a company proposing that physicians engage in the mass dispensing of prescription drugs to their patients, for profit. As we understand it, this company makes available precounted and prepackaged prescription drugs to physicians for this purpose.

Maryland law does not specifically prohibit authorized prescribers from personally preparing and dispensing prescriptions for their own patients, but there are certain requirements for labeling, record keeping, packaging, and cautions. The administration of medications in an office practice, hospital, or related institution; use of starter doses; dispensing of prescriptions in an emergency situation or when a pharmacy is not available within a ten-mile radius are not at issue here.

Our concern is with the mass distribution of prescription drugs to patients, for profit, as part of a physician's regular practice. We believe such practice is contrary to the patient's good health. It eliminates the pharmacist's role in drug monitoring and patient education and runs contrary to the well-established separate but complementary roles our two disciplines have evolved over many centuries of practice.

The "Physician/Pharmacists Code of Cooperation," adopted by our two associations, recognizes "the practice of medicine and pharmacy needs the combined services of both groups and drug dispensing by physicians should be discouraged if adequate pharmaceutical services are available."

I know the Board of Pharmacy is very concerned about this situation and is looking into the impact on the public. Those physicians who have received the solicitation from this company should be aware of these concerns and should understand that our associations and the regulatory boards are currently examining this situation.

DAVID A. BANTA **CAE, Executive Director**
Maryland Pharmaceutical Association

Hotline Numbers for Impaired Professionals
Physicians—727-0120
Dentists—964-2514
Attorneys—685-7878
Pharmacists—727-0746 or 528-7513

Emergency Psychiatric Beds 800-492-0610

Your Medical Faculty at Work

The Executive Committee met on Thursday, September 5 after the summer hiatus. It expressed its concern over escalating costs of professional liability insurance and heard presentations on how the quality of care, particularly for low-income and Medicaid patients, would be affected. It requested Faculty Subcommittee on Maternal Welfare chairman John Hawkinson MD to meet with Maryland Hospital Association representatives in an attempt to resolve the problem of providing obstetrical services in the rural communities.

In other areas of professional liability, the Executive Committee voted to employ public relations consultants to develop a program of increased publicity in these areas; authorized financial support for a one-day "teach-in" on this issue; and deferred other actions for Council consideration. Representatives of Maryland Blue Cross and Blue Shield attended the meeting to outline its proposal to the Health Care Financing Administration to become an "underwriter" rather than a fiscal intermediary for Medicare patients. No action was needed at this time, as the proposal was only in preliminary stages and appears to meet the Faculty's policy criteria on delivery of health care services.

The Executive Committee declined to change its policy with respect to physicians' dispensing drugs from their offices. The current policy is

> The Medical and Chirurgical Faculty of the State of Maryland believes that drug dispensing by physicians should be discouraged if adequate pharmaceutical service is available. A physician's professional income should be from the services he renders to his patients, and only from this source. (Physician/Pharmacist Code of Cooperation, *Compendium*, November 1984, p. 76.)

The Executive Committee approved a pilot project for the Montgomery County Medical Society dealing with collection of dues; designated the President-elect to represent the Faculty at the Governor's Task Force on Professional liability reform; set meeting dates for 1986; and authorized subcommittees to review and make recommendations in other areas of concern.

***JOHN SARGEANT* CAE**
Executive Director

Insurance Monitor

For more information or answers to your insurance questions, contact your insurance representative.

California Limits Lawyers' Fees

A 1975 law limiting lawyers' fees in medical malpractice cases has been upheld by the California Supreme Court. The law limits fees paid to plaintiff's attorneys to 40 percent of the first $50,000; 33 1/3 percent of the next $50,000; 25 percent of the next $100,000; and 10 percent of any amount over $200,000. In the majority opinion, Justice Otto M. Kaus noted that limiting attorneys' fees may deter attorneys from filing frivolous malpractice suits or encouraging their clients to hold out for unrealistically high settlements.

• • •

Hospitals Told to Screen Doctors

Attorney William H. Ginsburg of Los Angeles addressed the National Health Lawyers Association meeting in Washington and warned hospitals, health maintenance organizations, and other medical facilities to require that their physicians carry adequate malpractice insurance. Mr. Ginsburg noted that approximately 31 percent of all physicians are choosing to go without insurance coverage rather than pay the necessary premiums, a situation that could leave medical facilities bearing the burden if noninsured employees are sued. Mr. Ginsburg blamed the rising costs of malpractice insurance on the increasing number and severity of suits filed against physicians.

New York Passes Bill

The New York Legislature passed a bill addressing several medical malpractice issues. Effective July 1, 1985, the legislation requires hospitals to provide $1 million professional liability coverage for their affiliated physicians in addition to the $1 million physicians currently can purchase for themselves. The bill also replaced the standard one-third contingency fee for lawyers with a sliding-fee scale that reduces lawyers' fees on large awards. In addition, plaintiffs filing frivolous suits would be penalized up to $10,000. A proposed cap on awards for pain and suffering did not pass the Legislature.

• • •

Record Verdict

A Virginia jury recently awarded $8.3 million to the parents of a child who suffered severe brain damage when their obstetrician allegedly failed to arrive in time to attend the birth. The award, which included $2 million in punitive damages, was the largest malpractice verdict in Virginia history. Because the verdict far exceeded Virginia's $1 million statutory cap on awards, attorneys for the parents have asked that the cap be declared unconstitutional; a favorable ruling could mean the beginning of a number of large malpractice awards in the state.

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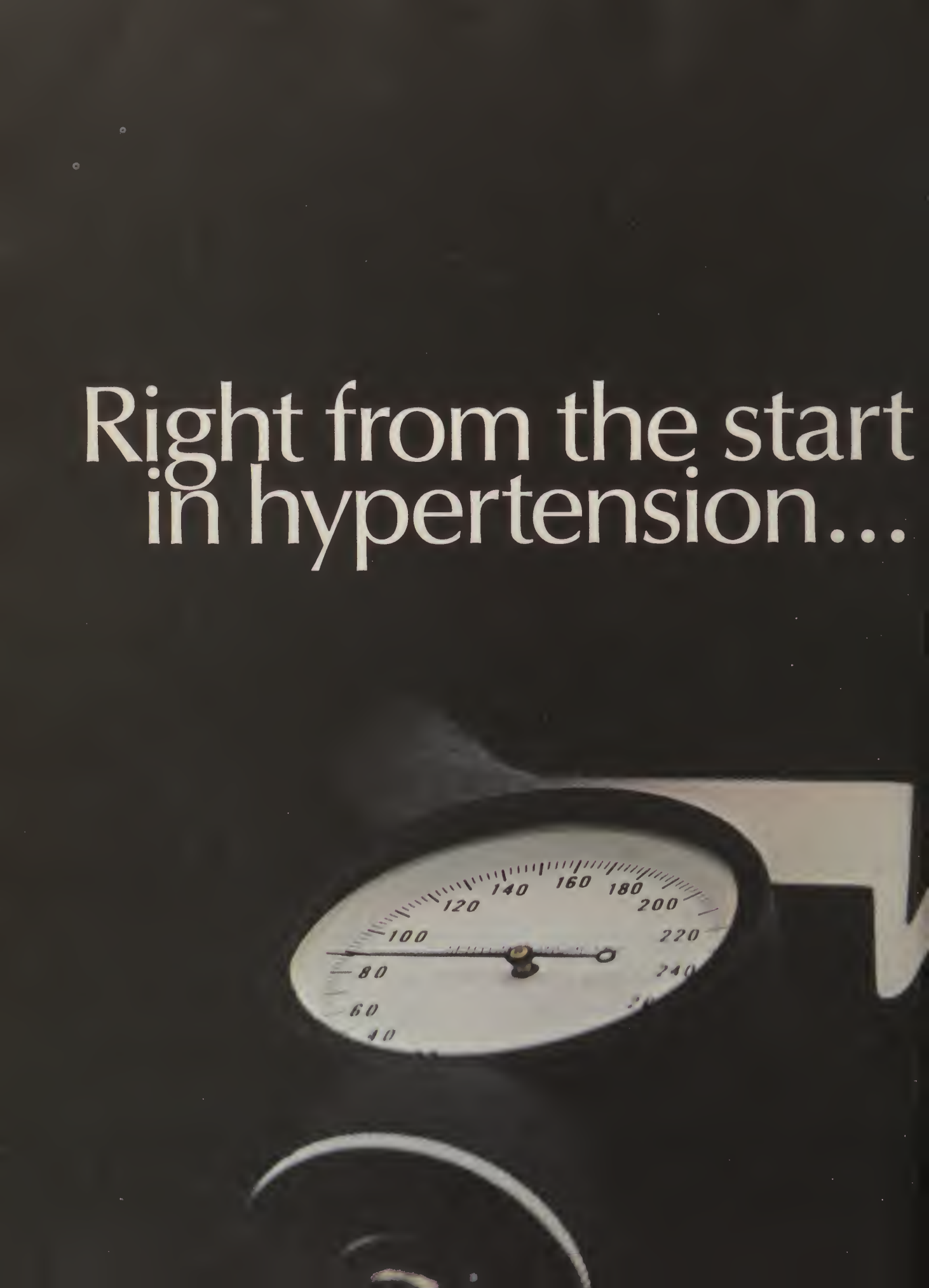
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J-5491 June 1985

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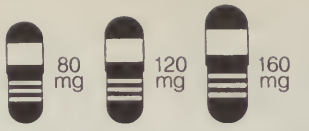


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BRIEF SUMMARY *(FOR FULL PRESCRIBING INFORMATION, SEE PACKAGE CIRCULAR.)*

INDERAL® LA brand of propranolol hydrochloride **(Long Acting Capsules)**

DESCRIPTION. Inderal LA is formulated to provide a sustained release of propranolol hydrochloride. Inderal LA is available as 80 mg, 120 mg, and 160 mg capsules.

CLINICAL PHARMACOLOGY. INDERAL is a nonselective beta-adrenergic receptor blocking agent possessing no other autonomic nervous system activity. It specifically competes with beta-adrenergic receptor stimulating agents for available receptor sites. When access to beta-receptor sites is blocked by INDERAL, the chronotropic, inotropic, and vasodilator responses to beta-adrenergic stimulation are decreased proportionately.

INDERAL LA Capsules (80, 120, and 160 mg) release propranolol HCl at a controlled and predictable rate. Peak blood levels following dosing with INDERAL LA occur at about 6 hours and the apparent plasma half-life is about 10 hours. When measured at steady state over a 24-hour period the areas under the propranolol plasma concentration-time curve (AUCs) for the capsules are approximately 60% to 65% of the AUCs for a comparable divided daily dose of INDERAL tablets. The lower AUCs for the capsules are due to greater hepatic metabolism of propranolol, resulting from the slower rate of absorption of propranolol. Over a twenty-four (24) hour period, blood levels are fairly constant for about twelve (12) hours then decline exponentially.

INDERAL LA should not be considered a simple mg for mg substitute for conventional propranolol and the blood levels achieved do not match (are lower than) those of two to four times daily dosing with the same dose. When changing to INDERAL LA from conventional propranolol, a possible need for retitration upwards should be considered especially to maintain effectiveness at the end of the dosing interval. In most clinical settings, however, such as hypertension or angina where there is little correlation between plasma levels and clinical effect, INDERAL LA has been therapeutically equivalent to the same mg dose of conventional INDERAL as assessed by 24-hour effects on blood pressure and on 24-hour exercise responses of heart rate, systolic pressure and rate pressure product. INDERAL LA can provide effective beta blockade for a 24-hour period.

The mechanism of the antihypertensive effect of INDERAL has not been established. Among the factors that may be involved in contributing to the antihypertensive action are (1) decreased cardiac output, (2) inhibition of renin release by the kidneys, and (3) diminution of tonic sympathetic nerve outflow from vasomotor centers in the brain. Although total peripheral resistance may increase initially, it readjusts to or below the pretreatment level with chronic use. Effects on plasma volume appear to be minor and somewhat variable. INDERAL has been shown to cause a small increase in serum potassium concentration when used in the treatment of hypertensive patients.

In angina pectoris, propranolol generally reduces the oxygen requirement of the heart at any given level of effort by blocking the catecholamine-induced increases in the heart rate, systolic blood pressure, and the velocity and extent of myocardial contraction. Propranolol may increase oxygen requirements by increasing left ventricular fiber length, end diastolic pressure and systolic ejection period. The net physiologic effect of beta-adrenergic blockade is usually advantageous and is manifested during exercise by delayed onset of pain and increased work capacity.

In dosages greater than required for beta blockade, INDERAL also exerts a quinidine-like or anesthetic-like membrane action which affects the cardiac action potential. The significance of the membrane action in the treatment of arrhythmias is uncertain.

The mechanism of the antimigraine effect of propranolol has not been established. Beta-adrenergic receptors have been demonstrated in the pial vessels of the brain.

Beta receptor blockade can be useful in conditions in which, because of pathologic or functional changes, sympathetic activity is detrimental to the patient. But there are also situations in which sympathetic stimulation is vital. For example, in patients with severely damaged hearts, adequate ventricular function is maintained by virtue of sympathetic drive which should be preserved. In the presence of AV block, greater than first degree, beta blockade may prevent the necessary facilitating effect of sympathetic activity on conduction. Beta blockade results in bronchial constriction by interfering with adrenergic bronchodilator activity which should be preserved in patients subject to bronchospasm.

Propranolol is not significantly dialyzable.

INDICATIONS AND USAGE. Hypertension: INDERAL LA is indicated in the management of hypertension; it may be used alone or used in combination with other antihypertensive agents, particularly a thiazide diuretic. INDERAL LA is not indicated in the management of hypertensive emergencies.

Angina Pectoris Due to Coronary Atherosclerosis: INDERAL LA is indicated for the long-term management of patients with angina pectoris.

Migraine: INDERAL LA is indicated for the prophylaxis of common migraine headache. The efficacy of propranolol in the treatment of a migraine attack that has started has not been established and propranolol is not indicated for such use.

Hypertrophic Subaortic Stenosis: INDERAL LA is useful in the management of hypertrophic subaortic stenosis, especially for treatment of exertional or other stress-induced angina, palpitations, and syncope. INDERAL LA also improves exercise performance. The effectiveness of propranolol hydrochloride in this disease appears to be due to a reduction of the elevated outflow pressure gradient which is exacerbated by beta-receptor stimulation. Clinical improvement may be temporary.

CONTRAINDICATIONS. INDERAL is contraindicated in 1) cardiogenic shock; 2) sinus bradycardia and greater than first degree block; 3) bronchial asthma; 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with INDERAL.

WARNINGS. CARDIAC FAILURE: Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or INDERAL should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of INDERAL therapy. Therefore, when discontinuance of INDERAL is planned the dosage should be gradually reduced over at least a few weeks, and the patient should be cautioned against interruption or cessation of therapy without the physician's advice. If INDERAL therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute INDERAL therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema)—PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA BLOCKERS. INDERAL should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

MAJOR SURGERY: The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

INDERAL (propranolol HCl), like other beta blockers, is a competitive inhibitor of beta-receptor agonists and its effects can be reversed by administration of such agents, e.g., dobutamine or isoproterenol. However, such patients may be subject to protracted severe hypotension. Difficulty in starting and maintaining the heartbeat has also been reported with beta blockers.

DIABETES AND HYPOGLYCEMIA: Beta-adrenergic blockade may prevent the appearance of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more difficult to adjust the dosage of insulin.

THYROTOXICOSIS: Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol does not distort thyroid function tests.

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

PRECAUTIONS. *General.* Propranolol should be used with caution in patients with impaired hepatic or renal function. INDERAL (propranolol HCl) is not indicated for the treatment of hypertensive emergencies.

Beta adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should be told that INDERAL may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

Clinical Laboratory Tests: Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS: Patients receiving catecholamine-depleting drugs such as reserpine should be closely observed if INDERAL is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

Pregnancy: Pregnancy Category C. INDERAL has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximum recommended human dose.

There are no adequate and well-controlled studies in pregnant women. INDERAL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: INDERAL is excreted in human milk. Caution should be exercised when INDERAL is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS. Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: bradycardia, congestive heart failure, intensification of AV block, hypotension; paresthesia of hands; thrombocytopenic purpura; arterial insufficiency, usually of the Raynaud type.

Central Nervous System: lightheadedness; mental depression manifested by insomnia, lassitude, weakness, fatigue; reversible mental depression progressing to catatonia; visual disturbances; hallucinations; an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Gastrointestinal: nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and sore throat, laryngospasm and respiratory distress.

Respiratory: bronchospasm.

Hematologic: agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-Immune: In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: alopecia, LE-like reactions, psoriasiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

DOSAGE AND ADMINISTRATION. INDERAL LA provides propranolol hydrochloride in a sustained-release capsule for administration once daily. If patients are switched from INDERAL tablets to INDERAL LA capsules, care should be taken to assure that the desired therapeutic effect is maintained. INDERAL LA should not be considered a simple mg for mg substitute for INDERAL. INDERAL LA has different kinetics and produces lower blood levels. Retitration may be necessary especially to maintain effectiveness at the end of the 24-hour dosing interval.

HYPERTENSION—*Dosage must be individualized.* The usual initial dosage is 80 mg INDERAL LA once daily, whether used alone or added to a diuretic. The dosage may be increased to 120 mg once daily or higher until adequate blood pressure control is achieved. The usual maintenance dosage is 120 to 160 mg once daily. In some instances a dosage of 640 mg may be required. The time needed for full hypertensive response to a given dosage is variable and may range from a few days to several weeks.

ANGINA PECTORIS—*Dosage must be individualized.* Starting with 80 mg INDERAL LA once daily, dosage should be gradually increased at three to seven day intervals until optimum response is obtained. Although individual patients may respond at any dosage level, the average optimum dosage appears to be 160 mg once daily. In angina pectoris, the value and safety of dosage exceeding 320 mg per day have not been established.

If treatment is to be discontinued, reduce dosage gradually over a period of a few weeks (see WARNINGS).

MIGRAINE—*Dosage must be individualized.* The initial oral dose is 80 mg INDERAL LA once daily. The usual effective dose range is 160-240 mg once daily. The dosage may be increased gradually to achieve optimum migraine prophylaxis. If a satisfactory response is not obtained within four to six weeks after reaching the maximum dose, INDERAL LA therapy should be discontinued. It may be advisable to withdraw the drug gradually over a period of several weeks.

HYPERTROPHIC SUBAORTIC STENOSIS—80-160 mg INDERAL LA once daily

PEDIATRIC DOSAGE—At this time the data on the use of the drug in this age group are too limited to permit adequate directions for use.

REFERENCES

1. Holland OB, Nixon JV, Kuhnert L: Diuretic-induced ventricular ectopic activity. *Am J Med* 1981;70:762-768. **2.** Holme I, Helgeland A, Hjermann I, et al: Treatment of mild hypertension with diuretics. The importance of ECG abnormalities in the Oslo study and in MRFIT. *JAMA* 1984;251:1298-1299.

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Osteoarthritis XII: Management of Low Back Pain

A. LEWIS KOLODNY MD and JACOB TENDLER MD

Arthritis is not the predominant cause of low back pain. Only one-third of patients displaying x-ray changes of osteoarthritis are symptomatic. Those presenting with pain may require considerable treatment since the pain may have multiple factors arising from degenerative disc disease, injury to soft tissue including paravertebral ligaments, and nerve root impingement. Spinal stenosis with compression of the spinal cord or occasionally the cauda equina may be secondary to osteoarthritic changes. This pathology is found more commonly in the cervical spine.

Dr. Kolodny is Co-Chief of Rheumatology at Franklin Square Hospital and Children's Hospital and Center for Reconstructive Surgery; he is also Chief of Rheumatology at North Charles General Hospital, Baltimore. Dr. Tendler is Assistant Professor of Psychiatry at The Johns Hopkins University School of Medicine, Baltimore.

Previous articles in this series relating to the problems of osteoarthritis have alluded to the involvement of the lumbar spine secondary to degenerative joint disease. However, despite the frequency of visible radiologic changes of osteoarthritis in the older population, arthritis is not the predominant cause of low back pain.

Today's climate of cost containment in rendering medical care makes accurate diagnosis essential for appropriate treatment. While the annual cost to the American public of arthritic disorders is estimated to be $16 billion, the cost of backache is also quite high, about $11 billion per year. This merely reflects the cost to industry of work loss. If workmen's compensation (which may range from $2.5 to $4.6 billion annually) and medical costs are factored in, the total cost brought about by industrially related backache in the United States may be $30 billion per year.[1-3] We cannot project costs of nonindustrial back pain. Furthermore, we cannot state the accuracy of these astronomical amounts today, since studies relating to costs were reported by Rowe in 1969,[4] Kelsey in 1979,[5] and Leavitt *et al.* in 1971,[6] but the costs of backache must be in the range mentioned. Benn and Wood in 1975[7] stated that 13 million workdays were lost annually in the United Kingdom. Costs of back pain in industrialized nations total a formidable amount. Before discussing the management of low backache, we review some basic data concerning the biomechanics of the spine, the multiple causes of back pain, and newer concepts of the pathophysiology of acute and chronic pain.

Biomechanics of the Lumbar Spine[8,9]

Pain arising from the lumbar spine may involve a number of anatomic structures (Table 1).

The design of the lumbar spine is such that flexion and extension are the prime motions; rotation is a potential problem. Maximum extension to flexion of the lumbar spine is 0 to 66 degrees. Backache may occur in the lower lumbar region as a result of excessive motion.

Stability of the lumbar spine is maintained by the anterior supporting structures. Stabilization of rotation is aided by the facet joints.

Bearing in mind the strengths and weaknesses of the lower back as pointed out in the summary of the anatomy and biomechanics of the lumbar spine, we point out a number of structural causes of low back pain and outline the many other diseases and disorders involved (Table 2, next page).

Another approach to the diagnosis of backache may be through the four T's: Tears (muscles and ligaments), Tumors, Trespassers (infection), and Trauma.

Pain arising from the lower back may be intrinsic, involving problems of posture and obesity, or extrinsic with pain secondary to visceral problems.

Determining the onset of pain and its duration can be useful in identifying the diagnosis and in deciding on the appropriate therapy. Nevertheless, one may be misled and may attribute acute pain to trauma when more serious underlying problems are the true cause of pain.

History

Obtaining a meticulous history is key to proper decision making. An orderly consideration of the numer-

Table 1. Structures Involved in Low Back Pain

1. Vertebral body
2. Vertebral neural arch
3. Intervertebral disc including the nucleus palposus and the annulus fibrosus
4. Facet joints (synovial joints) and their capsules
5. Ligaments—aid in motion but offer limited stability
   - Anterior and posterior longitudinal ligaments, supraspinous ligaments (inappropriate lifting and sitting may stretch posterior longitudinal ligament and cause back pain)
6. Iliolumbar ligament
7. Capsular system
8. Spinal cord, cauda equina, nerve roots, posterior primary ramus, anterior ramus, sinuvertebral nerve, and sympathetic nerve branches
9. Musculature
   (a) Erector spinae (maintainence of erect position and aids in flexion, lateral bending, and rotation)
   (b) Iliopsoas (stabilize posture)
   (c) Abdominal muscles (affect low back stability, reduce intradiscal pressure)

Table 2. Etiology of Low Back Pain[10]

A. Structural
  1. Spondylolithesis and spondylolysis
    (a) Dysplastic
    (b) Isthmic
    (c) Degenerative
    (d) Post-traumatic
    (e) Pathologic
  2. Lumbar spinal stenosis
    (a) Congenital-developmental
    (b) Acquired
    (c) Iatrogenic
    (d) Post-traumatic, late changes
    (e) Paget's disease
    (f) Fluorosis
  3. Prolapsed intervertebral disc
  4. Lumbosacral strain-sprain
  5. Osteoarthritis
  6. Diffuse idiopathic skeletal hyperostosis (DISH syndrome)
  7. Other congenital anomalies
    (a) Abnormal number of vertebrae
      Lumbarization of first sacral segment
      Sacralization of fifth lumbar
    (b) Spina bifida occulta
  8. Scoliosis
  9. Fractures
  10. Scheurmann's disease
B. Inflammatory
  1. Seronegative spondyloarthropathies
  2. Infection
C. Neoplastic
D. Metabolic
  1. Osteoporosis
  2. Osteomalacia
  3. Paget's disease
  4. Alkaptonuria (ochronosis)
  5. Chondrocalcinosis
  6. Gout (rare)
  7. Miscellaneous bone disease
E. Myofascial syndrome
F. Psychogenic rheumatism
G. Referred pain

Table 3. Physical Examination

A. Stance
B. Gait including walking on heels and toes
C. Range of motion and motor strength, examining the patient in positions of standing, sitting, supine, prone, and kneeling in a chair.
D. Palpation and determination of spinal curves—lordosis, scoliosis, and kyphosis.
E. Chest expansion
F. Circumference of extremities
G. Reflexes, straight leg raising, Patrick's
H. Further neurological examination if history or findings warrant
I. Peripheral pulses
J. Complete examination of other systems including rectal and pelvic examination
K. Meticulous examination of the skin
  1. Café au lait spots or birthmarks pointing at neurological or osseous disorders
  2. Pedunculated tumors suggesting neurofibromatosis
  3. Hairy faun's beard lesion: possible osseous disorder

ous causes of backache and use of the classification of backache will prevent inappropriate diagnosis and treatment. Often the history is more important than the physical examination. However, a careful examination can be carried out in a relatively brief time if one efficiently addresses the points brought out in Table 3.

Laboratory Tests

Appropriate x-ray and clinical laboratory tests are in order, but avoid expensive tests unless they are clearly indicated. In these days of "the bottom line is the dollar" we should adhere to reasonable principles of economy without sacrificing good medical judgment. Nevertheless, if first tests suggest specific diseases or disorders, more complex procedures should be considered. Initially, a complete blood count and erythrocyte sedimentation rate (ESR) should be ordered. The value of an ESR in investigating inflammatory disease is well recognized. For example, septic discitis may occur without fever, with a normal or slightly elevated white blood count, but with an elevated ESR. In this instance, blood cultures, disc biopsy, and culture are mandatory. Presence of an elevated serum calcium and elevated alkaline phosphatase might signal malignancy, Paget's disease, or other metabolic disease. A urinalysis might disclose abnormalities of the genitourinary tract. Suspicion of prostate malignancy calls for performance of an acid phosphatase test. Immunoelectrophoresis of proteins would be helpful if multiple myeloma is a possibility.

Radiologic examination can be deceptive, especially in older patients. Here osteoarthritic changes may be noted without these findings representing the true cause of the back pain. The presence of multiple disc space narrowing, however, cannot be ignored. Finding radiologic changes of osteoporosis, ankylosing spondylitis, spondylolithesis, kyphosis, Scheurmann's osteochondrosis, fractures, or lytic lesions is most likely indicative of the true cause of pain. Even so, spondylolysis, spondylolithesis, and congenital defects are noted in patients who have no back complaints.

The role of occupational stress in producing pain syndromes in persons with preexisting x-ray abnormalities is not always clear. Workers with any structural defect would seem to be at more risk. In 1984 Frymoyer *et al.*[11] studied a cohort of 321 men in an attempt to correlate positive x-ray findings with back pain. Relationship of severe low back pain to traction spurs, disc space narrowing, or both, between the fourth and fifth lumbar vertebrae seemed evident.

Use of CAT scan to clarify diagnosis where lesions are not clearly delineated by routing radiologic studies may reveal spinal stenosis, facet arthritis, and ruptured lumbar discs as well as other abnormalities. Techniques

using radioisotopes are particularly useful in inflammatory, septic, and neoplastic diseases. Our experience with the newer magnetic resonance studies is insufficient to establish its full diagnostic value in back pain, but we expect such testing may provide another valuable diagnostic tool. Thermography can be useful in disclosing inflammatory areas and radiculopathies. Electromyography and nerve conduction studies may be valuable in establishing causes of nerve and muscle pain. Invasive myelograms may be required when ruptured discs are suspected, provided surgical intervention is anticipated if such abnormalities are confirmed.

Approximately seven million x-rays of the lumbar spine are performed each year in this country. Some clinicians maintain that only one in two thousand x-rays of the lumbar spine influences eventual treatment. Nevertheless, to avoid missing serious disease such basic x-rays should be ordered for patients displaying persistent back pain.

Chronic Low Back Pain

A significant number of patients referred to us with chronic back pain have histories of industry related pain, acute trauma with secondary ruptured lumbar discs, strain-sprains, myofascial syndrome, psychogenic rheumatism, osteoporosis, and osteoarthritis. Less commonly encountered are ankylosing spondylitis, spinal stenosis, primary and secondary malignancies, Paget's disease, and other metabolic disorders. Intrinsic causes of back pain are frequently found in the obese patient with sagging abdominal muscles and droopy posture. Extrinsic causes of back pain arising in the genitourinary tract or involving aortic aneurysm are seen by us infrequently. Infection of the disc or vertebra occasionally is found. The presence of Klebsiella infections in heroin addicts should alert the clinician to consider this diagnosis. Because of increased occurrence of tuberculosis in immigrants from Haiti and other countries of the Caribbean, one should consider this potential infection of the spine.

Back pain related to occupational factors may arise from both trivial and serious injuries.[12] Underlying structural abnormalities and degenerative changes can at times represent risk factors. Other risk factors are represented in those workers with poor musculature and occupational hazards of heavy lifting, often carried out in an inappropriate manner.[12] Prolonged periods of sitting, frequent and prolonged lumbar flexion, and often a progressive, insidious loss of lumbar extension secondary to this prolonged flexion may contribute significantly to chronic low backache. Repetitive squatting, stooping, and bending can represent potential hazards of chronic back pain.

Psychosocial factors should be explored carefully as possible contributing factors in chronic backache. Smoking seems to represent a risk factor. This may be due in part to chronic cough, possibly because of the association of increased intradiscal pressure with coughing. Frymoyer *et al.*[11] have pointed out that thin, female smokers are at more risk of osteoporosis and collapsed vertebrae than are nonsmokers.

Various epidemiologic studies have been carried out in evaluating chronic low back pain. Accurate information is not always available from the employer. A survey carried out by one of the authors (ALK) in Maryland as part of the Governor's Task Force on Arthritis[13] revealed that most employers (at least in Maryland) kept very poor statistics concerning causes of sickness and injuries. This also applied to one of the state's largest employers, the state agencies. Nevertheless, other studies have indicated that among the work force 6 percent of workers suffer with chronic back pain. In this group, men outnumber women, and half of them are between 45 and 64 years old. Those with chronic back pain may have suffered between five and twenty years.[12]

Ruptured Lumbar Disc

Perhaps 5 to 8 percent of low back pain is caused by herniation of a lumbar disc. Most of these are found in males, more frequently in their early forties, although disc herniation may occur at any age. White,[14] Farfan,[15] Finneson,[16] Nachemson,[17,18] Naylor,[19] Kane,[20] Spengler,[21] and Williams,[22,23] have written extensively on this subject. While the etiology of intervertebral disc herniation is not fully understood, trauma, heredity, and biochemical changes in the disc may all play a role in the production of a herniated disc. Forces such as torsion play a significant part in bringing about a ruptured disc according to studies carried out by Farfan.[15] Spengler[21] opines that fatigue or repetitive submaximal loading can cause a tear in the periphery of the annulus fibrosus and eventually produce rupture of the disc.

Lumbar back pain secondary to discogenic disease has to be differentiated from spinal stenosis. Standing and walking may decrease disc pain but certainly increase pain secondary to stenosis. On the other hand, sitting may increase pain associated with a herniated disc, while pain due to stenosis is improved. The Valsalva maneuver, bending, and lifting worsen the pain of a ruptured disc but, in general, have less effect on the pain of spinal stenosis.

Certain danger signals occurring in suspected disc herniation should alert the surgeon as to the urgency of surgical intervention. These include impotence, blad-

der dysfunction, increased nocturnal pain with progressive symptoms, or neurological deficits including ankle clonus and decreased dorsiflexion of the ankle. Color changes in the leg may serve as a warning signal.

Chronicity of back pain often is attributed to changes following surgery for correction of ruptured disc or degenerative disc disease associated with osteoarthritis. In the first group psychological, social, and economic parameters must be considered before assuming failure of surgery. Nevertheless, a second herniated disc at a different level may be found with reexploration. The evaluation of a narrowed disc space secondary to degenerative arthritis must be strongly influenced by the knowledge that disc space narrowing as a reason for surgical intervention is inversely related to the age of the patient after the fourth decade. Prior to the fourth decade narrowing of the space may well indicate a potential reason for surgery.

Chronic Pain Syndrome

In 1979 the Subcommittee on Toxonomy of the International Association for the Study of Pain defined pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." If one views pain in this manner, one may better understand the interrelationship of psyche and soma in modifying the various manifestations of pain.

Behavioral psychologists have made significant contributions toward the treatment of chronic pain syndromes. Sternbach *et al.*[24–26] and Fordyce[27] have contributed greatly to our knowledge of pain. They are considered pioneers in the field of behavioral modification as related to chronic pain. They stressed the importance of psychosocial and interpersonal factors. Sternbach stated that "pain" is an abstraction of the many pains studied in different ways by different disciplines.

The psychoanalytic literature indicates the importance of unconscious mechanisms in enhancing and causing pain. Engel in 1959[28] suggested that conversion mechanisms played such a part. However, psychoanalytic concepts regarding the management of chronic pain disorders have been impractical in providing realistic alternatives in the clinical arena. Nevertheless, it is important to note that some psychoanalytic concepts have helped in understanding the reasons some patients are vulnerable to development of disability when suffering a chronic ailment.

External stress and/or inner conflict may elicit the somatization process with physiological expression of pain while masking the patient's awareness of the underlying problem.

Other disciplines following the pathways of Sternbach and Fordyce in studying and recognizing social and personal factors have learned more about disability and chronicity. This has resulted in increased sensitivity and realism among clinicians involved in treating pain syndromes. In past decades patients complaining of pain often were told, "It's all in your head." This attitude of omnipotence and escapism is not found commonly in practitioners today because the frustrations of ignorance are being supplanted by better understanding and alternatives. Carefully conceived pain centers provide a multidisciplinary approach to individualized pain therapy.

The differences between acute and chronic pain are well recognized today. Acute pain represents a signal of something going wrong. On the other hand, chronic pain is a false alarm where the underlying disease or disorder often is well known. Sternbach emphasized these points. Furthermore, the signs and symptoms of acute pain are those of anxiety, whereas the symptomatology of chronic pain is clearly that of depression.

Indeed, the pathways of acute and chronic pain differ. Acute pain traverses the neospinothalamic tract with influence of the reticular-activating system and the limbic system. The fibers synapse within the thalamus with transmission to the somatosensory cortex for final recognition of pain. Chronic pain moves through fibers in the older pathway, the paleospinothalamic tract with modification of pain perception in the hypothalamus, thalamus, and limbic systems before final transmission to the somatosensory cortex.

The gate-control model of pain modification as proposed by Melzack and Wall[29] has contributed greatly to our understanding of the central control processes of pain. Past experience may open or close the gate to pain. Nociceptive impulses moving along A delta and C fibers may be blocked by a barrage of stimuli moving through larger fibers so that pain impulses fail to pass through the gate transmission cells. Thus the acute pain of a needle prick in the finger may be blocked by rubbing the finger.

The role of the beta-lipotropin-endorphin systems in maintaining behavioral homeostasis and pain perception modulation has been studied extensively during the past decade.[30–32] Endorphins, enkephalins, and dynorphin enkephalins serve to modulate pain as the body's inner opioids. Furthermore, serotonin-containing neurons form an important link with the endorphin-enkephalin mediated analgesic systems in reducing the preception of pain.

Placebo effect may be physiological, brought on by the placebo suggestion traveling from the temporal lobe to the limbic system and the hypothalamus to stimulate the pituitary to form beta-endorphins.

Hendler[33] described the development of the chronic pain syndrome from acute pain through the various stages. Initially, acute pain may last up to two months without personality changes. The subacute stage (lasting from two to six months) is accompanied by irritability, increased somatization, anxiety, and insomnia. At this point the patient loses confidence in the ability of the physician and may seek other sources for help.

The chronic stage ranges from six months to eight years. Depression is noted, sometimes with anxiety. Definite personality changes occur with unresolved hostility, resentment, anger, and development of a high sense of entitlement. Hendler believes that at this point the patient becomes somewhat attached to the pain and may become passive-dependent.

During a period of three to twelve years, which Hendler labels as the subchronic stage, the patient may learn to function around the pain, even though there is no acceptance of the pain. Less sleep disturbance is present with a decrease in depression. Hypochondriasis is present with an increase in somatization. There may be some return in sexual activity, which may have markedly decreased in the previous stages.

Management of Back Pain

Total management of low back pain often is an interaction of many disciplines. Prevention of chronic low back disability represents the optimum measure and can be carried out through the cooperation of the primary physician, the industrial physician, the employer, and the epidemiologist. Adequate treatment after appropriate diagnosis is essential after preventive measures are established.

If pain persists the orthopedist, neurosurgeon, rheumatologist, physiatrist, physical therapist, occupational therapist, and nurse become a secondary team. If the patient's pain remains intractable, the cooperative efforts of psychiatrist, psychologist, family, employer, social, and vocational rehabilitation workers must be enlisted.

Early comprehensive evaluation, accurate diagnosis, and early appropriate treatment are key to preventing chronic pain syndromes. At this point therapy involves a number of principles (see Table 4).

Before performing any surgical procedure, consider psychogenic and compensation factors.

Control of chronic pain syndromes often is unsuccessful. Identification of patients displaying psychiatric vulnerabilities or premorbic psychopathology is most important, since treating both the psyche and the soma are key issues. In 1978 one of the authors (JT) developed a pain questionnaire useful in separating organic from psychogenic pain. A simple anatomic figure is used in his test, which is simple and concise. The test is self-administered and consists of four questions (see Figure, next page).

Table 4. Principles of Therapy for Back Pain

A. Proper bed rest
B. Analgesics
   1. Centrally acting analgesics for short-term use in severe pain[34,35]
   2. Peripherally acting analgesics, the nonsteroidal anti-inflammatory analgesics (NSAIDs)
   3. Muscle relaxants used in conjunction with analgesics
C. Proper physical therapy with appropriate exercises including postural exercises
D. Bracing and splinting with the help of the occupational therapist
E. Manipulation appropriately carried out can be helpful. Osteopathic physicians and our British colleagues use these methods more frequently. American orthopedists are beginning to follow these techniques in certain back injuries.
F. Trigger point injections including local anesthetic agents and corticosteroids
G. Specific antibiotic therapy for infection
H. Preventive and active treatment of osteoporosis
   1. Women over 30 years old require 1000 mg of calcium daily. If the patient is not on adequate dietary calcium, supplement with calcium carbonate.
   2. Postmenopausal women require 1500 mg of calcium daily. Vitamin D 50,000 units once a week, eventually reducing to once a month. The use of replacement estrogen and progesterone if there are no contraindications. In the presence of frequent fractures calcitonin and fluorides may be needed.
   3. A daily exercise program. Swimming is not appropriate since it does involve working against gravity.
   4. Men, because of larger bone mass, are less likely to develop osteoporosis before they reach the late sixties.
I. Ankylosing spondylitis requires not only the use of NSAIDs, such as phenylbutazone 100–300 mgs daily or indomethacin 150 mgs daily but also intensive physiotherapy with postural and breathing exercises. Clinical studies indicate many of the newer NSAIDs may be of value.
J. Correction of endocrine problems in presence of such disease
K. Surgical intervention as indicated
   1. Laminectomy
   2. Fusion
   3. Abscess drainage
   4. Chemonucleolysis with chymopapain
      Caveat: potential allergic reactions
   5. Posterior rhizotomy
   6. Facet joint blocks and surgery
   7. Caudal and epidural blocks

Tendler tested the reliability of the questionnaire by administering it to approximately 100 patients in the milieu of trauma centers and intensive care units. These patients suffered with gunshot wounds and multitrauma secondary to automobile accidents. Concomitantly, the same questionnaire was presented to 100 patients evaluated at the Chronic Pain Treatment Center at the Johns Hopkins Hospital.

Significantly, 72 percent of those patients suffering acute traumatic pain marked less than three descriptive pain terms in question #1. Similarly, appropriate anatomical dermatomes were indicated in question #2. Questions #3 and #4 were relatively irrelevant in this group of patients.

On the other hand, over 90 percent of those patients suffering from chronic pain circled more than three or four descriptive items in question #1 and failed to mark accurate or appropriate anatomical dermatomes in question #2. There was a definite tendency for this group of patients to color rather extensive areas of the body sketch. Answers to question #3 as to degree of

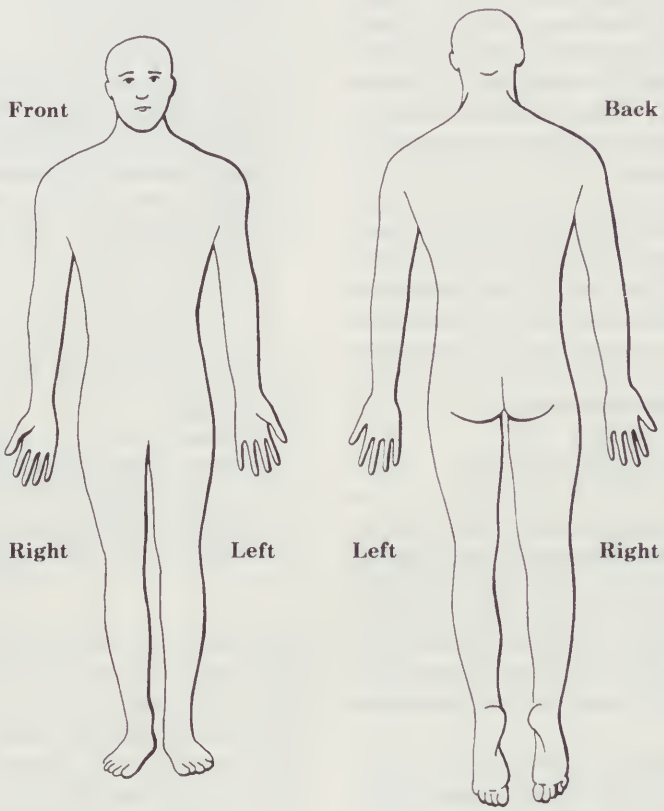
Figure. Pain Questionnaire

Name: _____ **History #** _____ **Date:** _____

1. Is your pain like: (circle as many as you wish)

BURNING	THROBBING	ACHING	STABBING	TINGLING	DULL
TWISTING	CRAMPING	CUTTING	SHOOTING	NUMBING	VAGUE
STINGING	SQUEEZING	PULLING	SMARTING	PRESSURE	COLDNESS
INDESCRIBABLE		OTHER: _____			

2. Where is your pain? (Please indicate on the diagram)



3. How is your pain now? (mark on any part of the line below)

No Pain ——————————— Severe Pain

4. How is your mood now? (Mark on any part of the line below)

Worse Mood ——————————— Best Mood

pain were invariably on the severe side of the analog scale. Question #4 was answered on the worse mood part of the scale.

Sternbach pointed out the importance of approaching the management of chronic pain through both peripheral and central nervous systems. Eliminating the pain source peripherally through physical measures is the best approach when possible. Through conditioning techniques, pain threshold can be raised. Hypnosis may be helpful in selected patients. At times electrical scrambling of the signal through use of the TENS unit can be helpful.

In the CNS, elimination of pain sources can be carried out through physical and psychological measures. Relaxation techniques and various medications may change pain threshold and perception. Since depression is the most common emotional disorder occurring in patients suffering the effects of chronic pain, the use of tricyclic antidepressants that release serotonin at the interneural synapse may modulate pain. Prescribing the precursor of serotonin, 1-tryptophan, may be useful. The coexistence of chronic pain and depression is always high (94 to 97 percent). Sternbach and his associates directly implicate decreased serotonin as a causative factor in both depression and chronic pain.

Amitriptyline and doxepan are known to decrease pain perception or increase pain thresholds by blocking the reuptake of serotonin in the synaptic cleft. While norepinephrine may be blocked to a lesser degree, it is believed to have an adverse effect on modulation of pain. One of the newer antidepressants, trazadone, having the advantage of being a pure serotonin inhibitor, is being prescribed more frequently for its reduction of pain perception. However, the untoward effect of priapism produced in 1:100,000 men reduces its use for males. This priapism becomes irreversible in six hours. If detected within the first six hours, this adverse effect can be offset by the use of amyl nitrite. Twelve cases of this drug-induced priapism have been reported in the United States.

Widespread use of antidepressants in managing chronic pain has stimulated important new research aimed toward mode of action and possible new uses of tricyclic antidepressants. New data concerning the neurophysiology of nociperception is somewhat controversial, but as knowledge accumulates, there appears to be much less disparity in interpretation of laboratory findings. Most investigators believe the tertiary amines are the most effective in modulating both chronic pain and depression.

Behavioral modification techniques are a prime method of treating chronic pain. Tapering the use of analgesics that act on the CNS is most important at this stage. Unfortunately, many patients suffering with chronic pain are addicted to this group of drugs. After withdrawal of these drugs, physicians must prescribe tricyclic antidepressants and institute psychiatric therapy for any hope of successful outcome. Often biofeedback techniques for relaxation training combined with aerobic conditioning are advisable. Finally, important forms of intervention are teaching patients to pace their activities and encouraging family counseling.

Conclusion

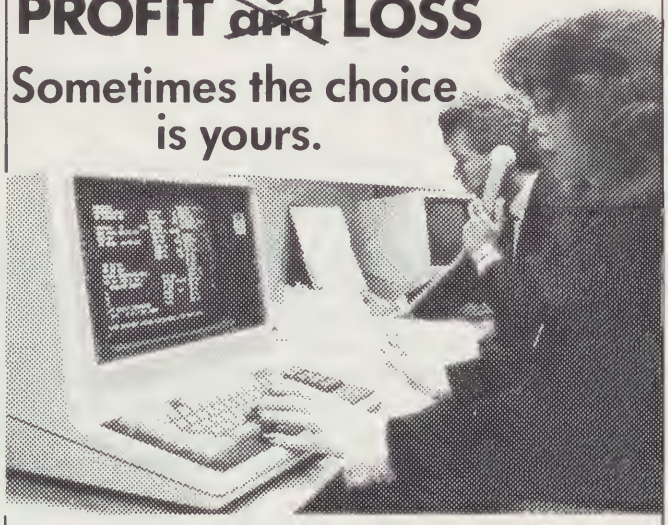
Control of chronic pain uses physiologic and psychologic measures. Psychologic forms of therapy include behavioral modification and cognitive techniques. Physiologic approaches include polypharmacologic modalities, surgical measures, physical and occupational therapy. Management of chronic low back pain requires a multidsicplinary, cooperative effort. The key to successful treatment requires a careful history, a meticulous physical examination, and appropriate investigative procedures to determine an accurate diagnosis. Early treatment is essential, but too often simple empiric therapy is unsuccessful.

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In the next few years, the SMA Committee on Dial Access envisioned nationwide expansion and tapes on subjects other than cancer. With grant support from the pharmaceutical industry, plans became reality. On June 1, 1978, the first SMA-sponsored tapes were made operational in Birmingham. With grant support from McNeil Laboratories, tapes on arthritis and rheumatism were produced at the University of Alabama in Birmingham (Editor Gene V. Ball MD).

Since 1978 seven disciplines have been added. Physicians at the M.D. Anderson Hospital, under Editor Joseph T. Painter MD, have continued to supply cancer tapes. Other prestigious institutions involved in the project are University of Alabama at Birmingham (diabetes and endocrinology, Editor Roy F. Roddam MD); Emory University School of Medicine (gastroenterology, Editor John T. Galambos MD); Ochsner Medical Institutions (infectious diseases, Editor George A. Pankey MD); University of Southern California School of Medicine (obstetrics and gynecology, Editor Paul F. Brenner MD); and Duke University Medical Center (psychotherapeutics, Editor John I. Walker MD).

Dial Access is a subscription service of the Education Department of the Southern Medical Association ($5 for members and $25 for nonmembers). The number of subscribers has grown to about 17,500. The subscriber receives a Ready Reference Catalog containing a special identification number, the toll-free telephone number, and a listing of the tapes. Calls may be placed to an operator seven days a week, 24 hours a day. The user indicates the number of the tape selected and is then connected to it. At this time a monograph of the script can be requested. When it arrives in a few weeks, the monograph serves as reinforcement to the information already received. About 80 percent of the callers request monographs, and the majority feel that monographs are an important part of the learning process.

The tapes are revised annually, and the expertise of the authors and editors ensures scientific accuracy. Records are kept by SMA regarding the number of calls to each discipline and each specific tape. These data are used when sections are revised to delete tapes not of interest to users and to ensure that the tapes most often used are kept current and clinically accurate.

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Since its inception Dial Access has received more than 225,000 calls. As Chairman of Southern Medical Association's Multi-Media Committee, I am proud of the contribution these calls have made to the continuing medical education of physicians and ultimately to the better treatment of their patients.

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Auxiliary

Don't Retire From Life—Share the Experience of a Lifetime

"Don't Retire From Life—Share the Experience of a Lifetime" is the theme of the AMA Auxiliary's 1985–86 Shape Up for Life Campaign. State and county auxiliary members will undertake a variety of service programs designed to improve the quality of life for older Americans in their communities.

The elderly are the fastest growing age group in the United States. Almost 28 million Americans are now over 65. By the year 2030, the number may increase to 65 million. Because of this growth, there is an urgent need for services that will allow older Americans to lead healthy, productive lives.

The American Medical Association Auxiliary, a volunteer organization of 80,000 physicians' spouses, launched its Shape Up for Life Campaign in 1979 to promote good health nationwide. This year's emphasis on community services for older Americans will promote programs in such areas as nutrition, physical fitness, safe use of drugs, accident prevention, and intergenerational programming. Other areas of need are meal programs, senior centers, friendly visiting, telephone reassurance, information/referral services, transportation services, vial of life (a plastic bottle filled with vital information which is placed in the refrigerator for the purpose of informing paramedical or emergency technicians), and involving older Americans.

In addition, auxiliary members will promote the positive aspects of aging. The public has many misconceptions about what it is like to grow old; this campaign will work to erase myths.

Health education not only informs, guides, and prevents health problems, but also it enhances the physician-patient relationship. Mutual respect and understanding are by-products of this communication. Senior participants become more aware of how to improve mental and physical capabilities and are motivated to be active, enthusiastic partners in their health care.

• • •

Anne Arundel County Auxiliary is a leader in providing services for the elderly through the Charles Ballard Senior Health Center, which opened in April 1983. The Center is open Tuesdays and Fridays.

On each Tuesday in September 1985 the Center offered a counseling seminar on "Personal Growth for Older Adults," given by Dr. Jon Williams, a clinical psychologist. The seminar was designed to help seniors become aware of their strengths, skills, and values and to teach them effective ways of communicating and relating to other people. It is the first stage in training peer counselors for work in other senior centers and respite care programs.

Ongoing programs consist of a variety of exercise activities: aerobics to music, arm exercises using dowel sticks and streamers, hula dancing, Greek circle dancing, and modified ballroom dance routines. Seniors monitor their resting and working pulse rate and learn methods of increasing exercise capacity while maintaining pulse within normal range.

There are periodic medical screening procedures for eyes, hearing, blood pressure, respiratory diseases, diabetes, dental, or podiatry problems.

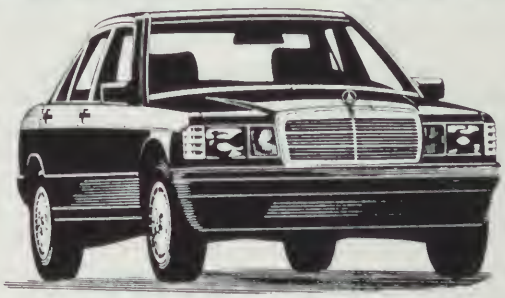
Auxiliary members actively involved with the Charles Ballard Senior Center are Ellenor Alvarez, Carol Friend, Helen Peters, and Joni Kitrinos.

Auxiliary to the Medical and Chirurgical Faculty of the State of Maryland. Mrs. Kathleen S. Karpers, President; Helen M. Reichel, Editor.

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The Library Page

A Caricaturist's View of French Physicians

The Library of the Medical and Chirurgical Faculty has five unusual prints in its History of Medicine and Rare Book Collection. Done by French caricaturist Adrien Barrère (1877–1931) in the early twentieth century, the prints are part of a series of six lithographs depicting Professors of the Faculty of Medicine and the School of Law in Paris. The library possesses all four medical prints as well as one of the legal prints.

Barrère's works come from a long tradition, in France and elsewhere, of satirizing the medical profession through caricature. Caricature appears in ancient Egyptian, Greek, and Roman art. Modern caricature began around 1500 and flourished with the rise of printing. While most caricatures were political in nature, the medical profession also was a frequent victim. Doctors often were portrayed as fools or quacks, con artists who made empty promises and administered ineffective treatments, or robbers who were more interested in a patient's money than in his health. Caricaturists mocked medicine and doctors in general and also attacked specific well-known physicians.[1,2]

A striking quality of the Barrère prints that sets Barrère apart from many of his predecessors is accuracy and attention to detail. The medical instruments and organs can be readily identified, and physical characteristics of the individual physicians are distorted very little. This is most likely due to Barrère's medical background and his familiarity with the physicians. Like earlier French medical caricaturists, Barrère sometimes emphasized sexual aspects of medicine. However, he was careful not to overdo it.

The first print in the series, *La Faculté de Médecine* (Figure 1), was done around 1903. Fifteen members of the Paris Medical Faculty are shown, many with a prop indicating their specialty. The physicians have a very stern, exaggeratedly dignified attitude; all are richly dressed under their surgeon's aprons. In the bottom right corner, an old man flees a proctoscope. A humorous miniature in a bottom corner is characteristic of these prints, appearing in all but one. The physicians are (from the left): André Chantenmesse (1851–1919), known for his work in bacteriology; Anne-Gabriel Pouchet (1851–1938), Professor of Pharmacology; Paul-Julien Poirier (1853–1907), surgeon and anatomist; Georges Dieulafoy (1839–1911), known for his work in internal medicine and for his theatrical personality; George-Maurice Debove (1845–1920), Professor of Clinical Medicine and known for advances in the field of dietetics; Paul Brouardel (1837–1906), Professor of Legal Medicine and author of monographs on death, hanging, strangulation, suffocation, drowning, and infanticide; Samuel-Jean Pozzi (1846–1918), general surgeon and gynecologist, and deviser of many technical procedures; Paul-Jules Tillaux (1834–1904), anatomist



Figure 1

Medical and Chirurgical Faculty of the State of Maryland Library, 1211 Cathedral Street, Baltimore, MD 21201. Joseph E. Jensen, Librarian

and surgeon; George Hayem (1841–1933), Professor of Therapeutics and a pioneer in internal medicine; André Victor Cornil (1837–1908), pathologist and Professor of Morbid Anatomy; Paul Berger (1845–1908), Professor of Clinical Surgery at the Hôpital Necker; Felix Guyon (1831–1920), genitourinary surgeon; Professor Lanois (1856–1920), histologist and endocrinologist; Adolphe Pinard (1844–1934), founder of the first child welfare clinic in France; and Pierre-Constant Budin (1846–1907), an obstetrician.[3]

Perhaps the most interesting print is *La Faculté et le Doyen* (Figure 2), done around 1907. While the other three prints are each a group of individual caricatures, this print portrays an event and shows the physicians interacting. Eugène Doyen (1859–1916) is shown demonstrating technique to several members of the Paris Medical Faculty. Doyen, inventor of elastic pressure forceps and other instruments, was known for his "sensational cinematographic methods."[4] Doyen often would film his operations for instructional purposes. His flamboyant style was criticized by many in the medical establishment. Barrère depicts the physicians grouped around Doyen, listening intently, in an arrangement reminiscent of Rembrandt's paintings of anatomy lessons. The scene is a joke; physicians of the Medical Faculty were critical of Doyen's methods. Cameras are clustered behind Doyen to photograph the procedure; sound recorders are placed beneath the table. The patient lies, complacently drugged, on the table. In the miniature at lower left, the woman is shown running from Death in the guise of a surgeon.

The physicians attending Doyen's production are: Paul-Ferdinand Segond (1851–1912), carrying a uterus on a myoma corkscrew, author of *Atlas Manuel de Technique Gynecologique*; Paul-Ferdinand Déjerine (1851–1912), neurologist; Felix-Joseph DeLapersonne (1853–1937), tall, with a forage cap, Professor of Clinical Ophthalmology; Louis-Joseph Landouzy (1845–1917), shown with bottles of mineral water, Dean of the Faculty and member of the section on clinical pathology; Ernest Gaucher (1854–1918), Professor of Dermatology and Syphilology; Charles-Marie Gariel (1841–1924), Professor of Medical Physics; Edouarde Brissaud (1852–1909), picking his neighbor's pocket, known for writings on cerebral anatomy and aphasia and editor of the *Revue Neurologique*; Nicolas-Augustine Gilbert (1858–1927), Professor of Clinical Medicine and Therapeutics; Jaques-Paul Reclus (1847–1927), with a syringe and having his pocket picked by Brissaud, Professor of Clinical Surgery; Georges Henri Roger (1860–1946), Professor of Experimental Pathology and member of the morbid anatomy section; Odilon-Marc Lannelonge (1840–1911), carrying a head, pathologist and collector of pathological specimens; Auguste Le-Dentu (1841–1926), Professor of Clinical Surgery; Charles Richet (1850–1935), carrying a clarinet and a small dirigible, Professor of Physiology and author of many novels, essays, and plays; Edouard Francis Kirmisson (1848–1927), Professor of Pediatric Surgery and orthopedic surgeon, shown with a whip and an artificial leg; Louis-Felix Terrier (1837–1908), writing "absolument, absolument" in his notebook, Professor of Operative Surgery and Appliances and of Clinical Surgery.

In *La Faculté de Médecine en Bocal* (The Faculty of Medicine in Bottles, Figure 3), pathology is the theme. The physicians portrayed are mostly pathologists and bacteriologists, and Barrère presents them as pathological specimens. The miniature in the bottom right cor-



Figure 2



Figure 3

ner is drawn to resemble a bacteria slide. In the midst of the bacteria a naked women floats. The physicians are: Fernand-Jules Bezançon (1868–1948), member of the section on medical pathology and shown in white with test tubes; Emile-Charles Achard (1860–1944), Professor of Pathology and Therapeutics; Fernand-Georges Widal (1862–1929), with a flower in his mouth and kidneys on a fork, known for discoveries leading to a vaccine for typhoid fever; Louis Prenant (1861–1927), Professor of Histology; Antonin Marfan (1858–1942), pediatrician and discoverer of Marfan's Syndrome, shown holding two Marfan's Syndrome children; Anatole Chauffard (1855–1932), carrying a flask of green liquid, Professor of the History of Medicine and Surgery; Paul Carnot (1869–1957), an enthusiast for opotherapy, shown carrying a pump and syringe; Edouarde Jeanselme (1858–1935), a syphilologist, leprologist and medical historian; Emile Sergent (1867–1943), shown with an x-ray tube, wrote on adrenal pathology; Louis-Henri Vaquez (1860–1936), member of the Therapeutics Section; Victor Balthazard (1872–1961), founder of the Institute de Médecine Legale, shown with a pistol, rope, and bloody knife; Marcel Labbé (1870–1939), carrying tongs, known for his work in nutritional disease.

In *Chirurgiens et Accoucheurs* (Surgeons and Obstetricians; Figure 4), Barrère repeats the specimen bottle motif. This is the last medical print. There is only one notable change in Barrère's style: the usual miniature in a bottom corner was omitted. Instead, a box of blood-stained medical instruments lies open in the foreground, and instruments are strewn about. The sur-



Figure 4

geons are dressed more like modern surgeons, and most are wearing overshoes. The physicians are: Bernard Cuneo (1873–1944), portrayed as Death holding a patched stomach, an academician in surgery; Antonin Gossett (1872–1944) holding a liver and forceps, a pupil of Terrier; Pierre-Alfred Duval (1874–1962), surgeon and obstetrician; Pierre Delbet (1861–1957), with bones and pins, inventor of the Delbet Plaster; Henri Hartmann (1860–1952), Professor in Operative Surgery at the Hôpital Bichat; Jean-Louis Faure (1863–1944), holding a uterus impaled on a corkscrew, known for his innovations in gynecology and hysterectomy; Lecène (unknown); Louis Ombrédanne (1871–1956), holding a bandaged child, interested in pediatric and plastic surgery; and Felix Legueu (1863–1939), genitourinary surgeon. At the right are a trio of obstetricians: Alexandre Couvelaire (1873–1948), Cyrille Jeannin (1874–1947), and Auguste Brindeau (1867–1960); all are shown with forceps.

A native of Paris, Adrien Barrère was a student of medicine and law, though he qualified in neither. His true talents were in art, and in 1902 he started publishing his work in French humor journals. Barrère produced many works during his life. During World War I he made 125 drawings for an *Album of the Soldier*, and in 1929 he exhibited at the Salons des Humoristes. However, the series on physicians and lawyers is by far his most famous work. The caricatures have been well received by the medical and legal professions. Over 420,000 prints were sold in a 25 year period, many to physicians and attorneys.[5] Apparently buyers were able to enjoy the satirization of their professions without taking offense at the sometimes grotesque portrayals.

***LISA A. MIX*, Assistant**
History of Medicine and Rare Book Collection

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3. Biographical facts about the physicians are taken from: Garrison, F.H., *The History of Medicine*, 3rd ed. (Philadelphia: Saunders and Co., 1921) and David LeVay, D. "Adrien Barrère, a French Medical Caricaturist," *Practitioner* 207(1971): 106–13; 239–43.

4. Garrison, *History of Medicine*. Garrison makes some critical comments about Doyen's methods, concluding that "the less showy the operating, the better the patient's chances."

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Selected Medical Literature Searches

The following are among the computerized medical literature searches provided to Med-Chi members during July 1985.

	No. of Citations
1. Dipyridamole and hypertension or cerebrovascular disorders	57
2. Duane's syndrome	13
3. Keratoacanthoma	30
4. Kidney calculi and ultrasonic therapy	16
5. Lactate dehydrogenase isoenzymes	40
6. Patient abuse	13
7. Quality of health care and health maintenance organizations	23
8. Squamous cell carcinoma of the breast	44
9. Treatment of depression and phobic disorders with alprazolam	31
10. Treatment of spontaneous pneumothorax	20

If you would like a copy of one of these searches or a search run on any biomedical topic, call or write the library.

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References:
1. Strauss WE, McIntyre KM, Parisi AF, et al: Safety and efficacy of diltiazem hydrochloride for the treatment of stable angina pectoris. Report of a cooperative clinical trial. Am J Cardiol 49:560-566, 1982.
2. Pool PE, Seagren SC, Bonanno JA, et al: The treatment of exercise-inducible chronic stable angina with diltiazem: Effect on treadmill exercise. Chest 78 (July suppl):234-238, 1980.

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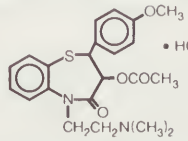
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CLINICAL PHARMACOLOGY

The therapeutic benefits achieved with CARDIZEM are believed to be related to its ability to inhibit the influx of calcium ions during membrane depolarization of cardiac and vascular smooth muscle.

Mechanisms of Action. Although precise mechanisms of its antianginal actions are still being delineated, CARDIZEM is believed to act in the following ways:

1. Angina Due to Coronary Artery Spasm: CARDIZEM has been shown to be a potent dilator of coronary arteries both epicardial and subendocardial. Spontaneous and ergonovine-induced coronary artery spasm are inhibited by CARDIZEM.
2. Exertional Angina: CARDIZEM has been shown to produce increases in exercise tolerance, probably due to its ability to reduce myocardial oxygen demand. This is accomplished via reductions in heart rate and systemic blood pressure at submaximal and maximal exercise work loads.

In animal models, diltiazem interferes with the slow inward (depolarizing) current in excitable tissue. It causes excitation-contraction uncoupling in various myocardial tissues without changes in the configuration of the action potential. Diltiazem produces relaxation of coronary vascular smooth muscle and dilation of both large and small coronary arteries at drug levels which cause little or no negative inotropic effect. The resultant increases in coronary blood flow (epicardial and subendocardial) occur in ischemic and nonischemic models and are accompanied by dose-dependent decreases in systemic blood pressure and decreases in peripheral resistance.

Hemodynamic and Electrophysiologic Effects. Like other calcium antagonists, diltiazem decreases sinoatrial and atrioventricular conduction in isolated tissues and has a negative inotropic effect in isolated preparations. In the intact animal, prolongation of the AH interval can be seen at higher doses.

In man, diltiazem prevents spontaneous and ergonovine-provoked coronary artery spasm. It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure and, in exercise tolerance studies in patients with ischemic heart disease, reduces the heart rate-blood pressure product for any given work load. Studies to date, primarily in patients with good ventricular function, have not revealed evidence of a negative inotropic effect; cardiac output, ejection fraction, and left ventricular end diastolic pressure have not been affected. There are as yet few data on the interaction of diltiazem and beta-blockers. Resting heart rate is usually unchanged or slightly reduced by diltiazem.

Intravenous diltiazem in doses of 20 mg prolongs AH conduction time and AV node functional and effective refractory periods approximately 20%. In a study involving single oral doses of 300 mg of CARDIZEM in six normal volunteers, the average maximum PR prolongation was 14% with no instances of greater than first-degree AV block. Diltiazem-associated prolongation of the AH interval is not more pronounced in patients with first-degree heart block. In patients with sick sinus syndrome, diltiazem significantly prolongs sinus cycle length (up to 50% in some cases).

Chronic oral administration of CARDIZEM in doses of up to 240 mg/day has resulted in small increases in PR interval, but has not usually produced abnormal prolongation. There were, however, three instances of second-degree AV block and one instance of third-degree AV block in a group of 959 chronically treated patients.

Pharmacokinetics and Metabolism. Diltiazem is absorbed from the tablet formulation to about 80% of a reference capsule and is subject to an extensive first-pass effect, giving an absolute bioavailability (compared to intravenous dosing) of about 40%. CARDIZEM undergoes extensive hepatic metabolism in which 2% to 4% of the unchanged drug appears in the urine. In vitro binding studies show CARDIZEM is 70% to 80% bound to plasma proteins. Competitive ligand binding studies have also shown CARDIZEM binding is not altered by therapeutic concentrations of digoxin, hydrochlorothiazide, phenylbutazone, propranolol, salicylic acid, or warfarin. Single oral doses of 30 to 120 mg of CARDIZEM result in detectable plasma levels within 30 to 60 minutes and peak plasma levels two to three hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3.5 hours. Desacetyl diltiazem is also present in the plasma at levels of 10% to 20% of the parent drug and is 25% to 50% as potent a coronary vasodilator as diltiazem. Therapeutic blood levels of CARDIZEM appear to be in the range of 50 to 200 ng/ml. There is a departure from dose-linearity when single doses above 60 mg are given; a 120-mg dose gave blood levels three times that of the 60-mg dose. There is no information about the effect of renal or hepatic impairment on excretion or metabolism of diltiazem.

INDICATIONS AND USAGE

1. **Angina Pectoris Due to Coronary Artery Spasm.** CARDIZEM is indicated in the treatment of angina pectoris due to coronary artery spasm. CARDIZEM has been shown effective in the treatment of spontaneous coronary artery spasm presenting as Prinzmetal's variant angina (resting angina with ST-segment elevation occurring during attacks).
2. **Chronic Stable Angina (Classic Effort-Associated Angina).** CARDIZEM is indicated in the management of chronic stable angina. CARDIZEM has been effective in controlled trials in reducing angina frequency and increasing exercise tolerance.

There are no controlled studies of the effectiveness of the concomitant use of diltiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities.

CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

WARNINGS

1. **Cardiac Conduction.** CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0.48%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed periods of asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.
2. **Congestive Heart Failure.** Although diltiazem has a negative inotropic effect in isolated animal tissue preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-blockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients.
3. **Hypotension.** Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic hypotension.
4. **Acute Hepatic Injury.** In rare instances, patients receiving CARDIZEM have exhibited reversible acute hepatic injury as evidenced by moderate to extreme elevations of liver enzymes. (See PRECAUTIONS and ADVERSE REACTIONS.)

PRECAUTIONS

General. CARDIZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS).

Controlled and uncontrolled domestic studies suggest that concomitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diltiazem has been shown to increase serum digoxin levels up to 20%.

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vitro bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and fetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women; therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outweigh its potential risks in this situation.

Pediatric Use. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded.

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy.

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established. The most common occurrences, as well as their frequency of presentation, are: edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), asthenia (1.2%), AV block (1.1%). In addition, the following events were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrence.

Cardiovascular:	Flushing, arrhythmia, hypotension, bradycardia, palpitations, congestive heart failure, syncope.
Nervous System:	Paresthesia, nervousness, somnolence, tremor, insomnia, hallucinations, and amnesia.
Gastrointestinal:	Constipation, dyspepsia, diarrhea, vomiting, mild elevations of alkaline phosphatase, SGOT, SGPT, and LDH.
Dermatologic:	Pruritus, petechiae, urticaria, photosensitivity.
Other:	Polyuria, nocturia.

The following additional experiences have been noted:

A patient with Prinzmetal's angina experiencing episodes of vasospastic angina developed periods of transient asymptomatic asystole approximately five hours after receiving a single 60-mg dose of CARDIZEM.

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: erythema multiforme; leukopenia; and extreme elevations of alkaline phosphatase, SGOT, SGPT, LDH, and CPK. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

OVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with oral diltiazem has been limited. Single oral doses of 300 mg of CARDIZEM have been well tolerated by healthy volunteers. In the event of overdosage or exaggerated response, appropriate supportive measures should be employed in addition to gastric lavage. The following measures may be considered:

Bradycardia	Administer atropine (0.60 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.
High-Degree AV Block	Treat as for bradycardia above. Fixed high-degree AV block should be treated with cardiac pacing.
Cardiac Failure	Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics.
Hypotension	Vasopressors (eg, dopamine or levarterenol bitartrate).

Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating physician.

The oral/LD_{50}'s in mice and rats range from 415 to 740 mg/kg and from 560 to 810 mg/kg, respectively. The intravenous LD_{50}'s in these species were 60 and 38 mg/kg, respectively. The oral LD_{50} in dogs is considered to be in excess of 50 mg/kg, while lethality was seen in monkeys at 360 mg/kg. The toxic dose in man is not known, but blood levels in excess of 800 ng/ml have not been associated with toxicity.

DOSAGE AND ADMINISTRATION

Exertional Angina Pectoris Due to Atherosclerotic Coronary Artery Disease or Angina Pectoris at Rest Due to Coronary Artery Spasm. Dosage must be adjusted to each patient's needs. Starting with 30 mg four times daily, before meals and at bedtime, dosage should be increased gradually (given in divided doses three or four times daily) at one- to two-day intervals until optimum response is obtained. Although individual patients may respond to any dosage level, the average optimum dosage range appears to be 180 to 240 mg/day. There are no available data concerning dosage requirements in patients with impaired renal or hepatic function. If the drug must be used in such patients, titration should be carried out with particular caution.

Concomitant Use With Other Antianginal Agents:

1. **Sublingual NTG** may be taken as required to abort acute anginal attacks during CARDIZEM therapy.
2. **Prophylactic Nitrate Therapy**—CARDIZEM may be safely coadministered with short- and long-acting nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.
3. **Beta-blockers.** (See WARNINGS and PRECAUTIONS.)

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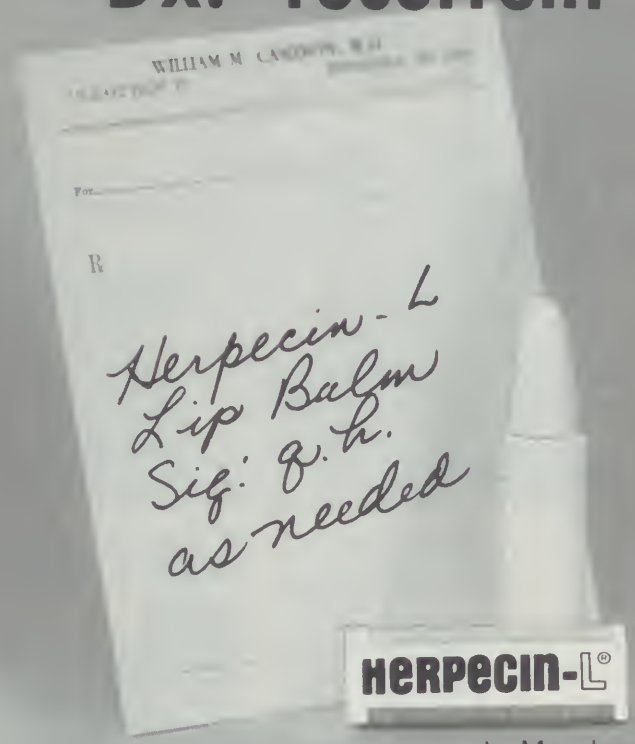
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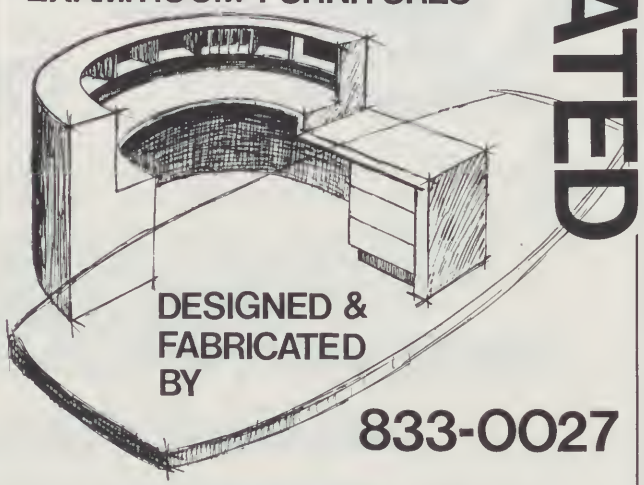
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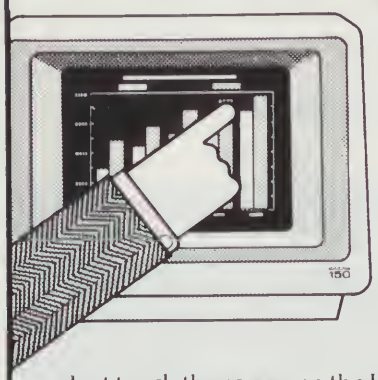
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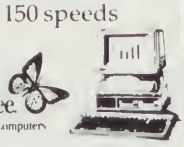
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Discipline Commission Action

In the Matter of
Matthew S. Atkinson, III, MD
Before the
Commission on Medical Discipline

Findings of Fact, Conclusions of Law and Order

On April 8, 1985, the Commission ordered the emergency suspension of Respondent's license to practice medicine by the authority of State Government Article, §10-405. Written notice of the suspension was provided to Respondent, and Respondent requested a hearing on the emergency suspension.

A hearing on the emergency suspension was held on June 4, 1985.

Findings of Fact

Based on the information known and available to it, the Commission finds that:

1. At all times relevant to the case, Respondent was a physician licensed to practice in the State of Maryland.
2. Respondent received a psychiatric evaluation from Jonas R. Rappeport MD based on an examination that occurred on March 21, 1985.
3. Respondent was judicially determined to be incompetent to manage his affairs and that Frank H. Newell, III and Martha Atkinson have been appointed guardians of the property for Respondent.
4. Based on the uncontroverted testimony, Respondent suffers from a psychiatric illness, and that in the opinion of Dr. Rappeport, who has qualified as an expert witness of the field of psychiatry, as a result of that condition Respondent is mentally incompetent to practice medicine; and there is a risk to public health and safety if Respondent is permitted to continue to practice medicine.

Conclusions of Law

Based on the foregoing Findings of Fact, the Commission finds that Respondent is mentally incompetent to practice medicine, and that there is a risk to public health and safety if Respondent is permitted to continue to practice medicine.

Order

Based on the foregoing Findings of Fact and Conclusions of Law, it is this 18th day of June 1985, by a majority vote of those members of the Commission on Medical Discipline considering this case, hereby

ORDERED that the license of the Respondent Matthew S. Atkinson, III to practice medicine shall be SUSPENDED.

HILARY T. O'HERLIHY **MD, Chairman**
Commission on Medical Discipline

On instruction of the Council of the Medical and Chirurgical Faculty of the State of Maryland, "Findings of Fact, Conclusions of Law, and Order" will be published in the Maryland Medical Journal.

In the Matter of
Reza Feiz MD
Before the
Commission on Medical Discipline

Findings of Fact, Conclusions of Law and Order

Based on information coming to its attention, the Commission on Medical Discipline of Maryland (the "Commission") conducted an investigation and subsequently determined to charge Reza Feiz MD ("Respondent") with violation of the Maryland Medical Practice Act, Health-Occupations Article, Maryland Code Annotated, §14-504(6) as follows:

> Is convicted of or pleads guilty or nolo contendere with respect to a crime involving moral turpitude . . .

Respondent was notified of the charges by letter dated April 22, 1985. A hearing was scheduled for June 18, 1985. On May 21, 1985, a prehearing conference was held. Attending were Respondent, Marna McLendon, counsel for Respondent, Judith K. Sykes, Assistant Attorney General and Administrative Prosecutor; and Karl F. Mech MD, Executive Secretary, member and designee of the Commission. As a result of discussions and negotiations at the pre-hearing conference, Respondent agreed to enter into the following Consent Order.

Findings of Fact

Based upon the information in its files, and otherwise made known to it, the Commission finds:

1. That Respondent, Reza Feiz MD, is a physician licensed and practicing in Maryland currently and at all times material to the allegations relating to the above matter.
2. That on July 18, 1984, Respondent pled guilty by way of an Alford Plea, in the District Court of Maryland for the District of Howard County to a criminal charge against him of 4th degree sexual offense that alleged he engaged in sexual contact with a certain person against her will and without her consent in violation of Article 27, Section 464C of the Maryland Annotated Code.
3. The Statement of Facts in support of the Plea indicated that on February 11, 1984 Respondent touched a 15-year-old girl in her breast area several times and that he did so against her will and without her consent. Respondent, whose specialty is child and adolescent psychiatry, had been the coordinating psychiatrist for the girl during a nine-month period ending in March 1983, when she was institutionalized in a private facility, and upon her release had prescribed medications for her on three occasions, the last time being in June 1983. Subsequently, there were several telephone conversations believed to be of a "friendship" type. During one of those conversations the meeting at which the incident occurred was arranged.
4. That said charge related to a crime of moral turpitude.
5. That on August 15, 1984, Respondent was found

guilty by the District Court of Maryland for the District of Howard County. The imposition of sentence was suspended, however, and Respondent was placed on nonactive probation under the supervision of the Maryland Division of Parole and Probation for a period of 36 months. The Court, having reviewed both a psychiatric and a psychological report as well as numerous letters praising Dr. Feiz's professional competence, felt that Dr. Feiz did not need supervision nor any special conditions of probation. The only condition imposed was that he obey all laws, and a record check was ordered to be made every 6 months.

6. That the incident in question did not involve use of violence or force.

7. That Dr. Feiz's supervisor at the time of the incident, who worked with him for seven years, found him to be a competent, energetic, and caring psychiatrist committed to high quality patient care. To the knowledge of that supervisor, the incident that forms the basis of the charges in this case was the only occasion on which Dr. Feiz deviated from a high standard of professional ethics, and he was known among those with whom he worked as a dedicated physician with high moral codes and personal integrity.

8. That Respondent has complied with the terms of his probation.

9. That psychiatric evaluations of Respondent on May 31, 1984 and on May 13, 1985 and psychological reports dated July 27 and October 18, 1984 found no evidence of a psychosexual, paraphiliac, or personality disorder, and concluded that repetition of the incident was unlikely, but recommended psychotherapy on an ongoing basis to help Respondent deal with certain problems he was having.

10. That Respondent has followed up on that recommendation and except for a period of time when he was out of the country, has been receiving ongoing psychotherapy since May 18, 1984.

11. Respondent resigned in April 1984 from the position he occupied at the time the incident occurred and remained unemployed until April 8, 1985, at which time he assumed the position of staff psychiatrist at Eastern Shore Hospital Center where he is working with adults under supervision.

Conclusions of Law

Based on the foregoing Findings of Fact, the Maryland Commission on Medical Discipline, by unanimous vote of those members considering the above case concludes as a matter of law that Respondent violated §14-504(6) of the Maryland Medical Practice Act, Health-Occupations Article, Maryland Code Annotated and finds Respondent GUILTY of that charge.

Order

Based upon the foregoing Findings of Fact and Conclusions of Law it is this 18th day of June 1985, by unanimous vote of those members of the Maryland Commission on Medical Discipline who considered the above case,

ORDERED that the license of Respondent Reza Feiz MD, an individual licensed to practice medicine in Maryland, is hereby SUSPENDED; and be it further

ORDERED that the suspension of Respondent's license shall be immediately STAYED and Respondent placed on PROBATION subject to the following conditions:

1. That Respondent shall not engage in activities of the type that led to his criminal conviction.

2. That Respondent obey all laws.

3. That Respondent arrange for the results of the record checks performed as a condition of his Court-ordered probation to be forwarded to the Commission.

4. That Respondent continue with his treating psychotherapist until the Commission is notified by the treating psychiatrist that such treatment is no longer recommended and the Commission is in agreement with that recommendation.

5. That Respondent shall arrange for the forwarding of a psychiatric report to the Commission every 6 months for the duration of his probation period.

6. That Respondent may practice only under supervision either in his present setting or under an alternative arrangement that has been approved by the Commission.

7. That Respondent will not, without Commission approval, undertake to treat on a regular basis children or adolescents. Respondent may apply to the Commission for such approval at any time during the period of his probation. Approval will be contingent on receipt by the Commission of a written communication from Respondent's psychotherapist in support of the application and may be subject to specified conditions.

8. That Respondent arrange for his supervisor to forward a report as to his performance every 6 months for the duration of his probation; and be it further

ORDERED, that three years from the date of this Order the Commission will entertain a petition for termination of Respondent's probationary status and for restoration of his license to practice without condition or restriction, upon Respondent's demonstrating to the satisfaction of the Commission that he has complied with the terms and conditions of his probation. If the Commission determines that he has not complied with the terms and conditions of his probation, the Commission may modify one or more of the conditions of his probation; and be it further

ORDERED that if Respondent violates any of the foregoing conditions of probation, the Commission, after notification, a hearing, and determination of violation, may impose any disciplinary sanctions it deems appropriate.

HILARY T. O'HERLIHY **MD, Chairman**
Commission on Medical Discipline of Maryland

Consent

By this Consent, I hereby admit the truth of the Findings of Fact and accept and submit to the foregoing Order and its conditions. I have read and acknowledge the validity of the Order as if made after a hearing in which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my behalf, and to all other substantive and procedural protections provided by law. I also recognize that I am waiving my right to appeal any adverse ruling of the Commission that might have followed any such hearing. By this Consent, I understand that I am waiving all such rights. I sign this Consent without reservation and after conferring with counsel and I fully understand its meaning.

REZA FEIZ **MD**

• • •

In the Matter of Raja I. Hawit MD Before the Commission on Medical Discipline

Notification of Termination of Probation and Reinstatement of Medical License

By Order dated July 13, 1981 (the "1981 Order"), the Commission on Medical Discipline (the Commission) found Raja I. Hawit MD (the "Respondent") guilty of violating Article 43, §130(h)(4) of the Annotated Code (recodified at §14-504(6) of the Health Occupations Article). The Commission revoked the medical license of the Respondent, but stipulated that as of July 13, 1981, the revocation be stayed and that Respondent be placed on probation for a three-year period subject to certain conditions (the "Conditions of Probation"). The Order further provided that if Dr. Hawit complied satisfactorily with the Conditions of Probation, his license to practice medicine in the State of Maryland would be reinstated.

On July 13, 1984,* the medical license of Raja I. Hawit MD was automatically reinstated in the State of Maryland without any conditions or restrictions whatsoever.

HILARY T. O'HERLIHY **MD, Chairman**
Commission on Medical Discipline of Maryland

• • •

In the Matter of Joseph Jack, Jr., MD Before the Commission on Medical Discipline

Order Terminating Probation and Reinstating License

By Order dated March 21, 1978 (the "1978 Order") the Commission on Medical Discipline (the "Commission") found Joseph Jack, Jr., MD (the "Respondent") guilty of violating Article 43, §130(h)(18) (recodified at the Maryland Annotated Code, Section 14-504(4) of the Health Occupations Article) and revoked the medical license of Respondent subject to certain conditions (the "Conditions of Probation"). The Order further provided that if Respondent complied satisfactorily with the Conditions of Probation the Commission would entertain a petition for termination of Respondent's probationary status in two years and reinstatement of his medical license without any conditions or restrictions. On July 15, 1985, Respondent petitioned the Commission for reinstatement of his license to practice medicine in Maryland without any conditions or restrictions. At its meeting on July 16, 1985, the Commission reviewed Respondent's petition for reinstatement. Based on its review of the petition, the Commission determined that Respondent had fulfilled the Conditions of Probation contained in the 1978 Order.

Findings of Fact

The Commission finds that Respondent has satisfactorily complied with all the Conditions of Probation imposed by the Commission's 1978 Order.

Conclusions of Law

The Commission concludes, as a matter of law, that it is appropriate to terminate Respondent's Conditions of Probation and to reinstate his license without any condition or restriction.

Order

Upon the foregoing Findings of Fact and Conclusions of Law, it is this 16th day of July 1985 by a unanimous vote of a quorum of the Commission:

ORDERED that effective as of the date of this Order, the Conditions of Probation imposed on Respondent's practice of medicine by the Commission's 1978 Order are hereby TERMINATED and of no further force and effect; and be it further

ORDERED that Respondent's license to practice medicine in the State of Maryland be REINSTATED without any condition or restriction whatsoever.

HILARY T. O'HERLIHY **MD, Chairman**
Commission on Medical Discipline of Maryland

• • •

* Received in *MMJ* office 8/2/85

In the Matter of John Dean Wilson MD Before the Commission on Medical Discipline

Findings of Fact, Conclusions of Law and Order

Upon certain information coming to the attention of the Commission on Medical Discipline (the "Commission"), the Commission requested that the Peer Review Committee of the Medical and Chirurgical Faculty of the State of Maryland ("Med Chi") investigate the practice of John Dean Wilson ("Respondent"). After the investigation and the receipt of Med Chi's report, the Commission determined to charge Respondent with violation of Section 15-504(4) of the Medical Practice Act, Health Occupations Article of the Annotated Code of Maryland.

Findings of Fact

Based on the information known and available to it, the Commission finds that:

1. At all times relevant to the case, Respondent was a physician licensed to practice in the State of Maryland.

2. That four reviews of Respondent's records by members of the Peer Review Committee of Med Chi revealed that Respondent failed to keep adequate records. In particular, Respondent failed to record pertinent subjective and objective findings sufficient to permit another physician to evaluate and understand the basis for his diagnosis and treatment plan. In the absence of such information, the finding is that either appropriate diagnostic procedures were not performed or, if done, the necessary data were not recorded.

3. Respondent prescribed medications frequently by telephone without seeing patients and without monitoring the effectiveness of the medications.

Respondent failed to recognize serious illness in the case of Patient A.** Respondent prescribed penicillin for Patient A without having seen her. Subsequently, after having seen her, Respondent diagnosed her as having hepatitis without having laboratory studies done. After having been admitted to Washington County Hospital, Patient A was diagnosed by others as suffering from sepsis. Upon autopsy, it was determined that sepsis was caused by a ruptured sigmoid diverticulum with peritonitis.

4. Respondent failed to recognize serious illness and failed to obtain adequate assistance of a consulting physician in the case of Patient B. Patient B was admitted by Respondent to Washington County Hospital with a diagnosis of pelvic inflammatory disease. Patient B was not seen by a surgeon until November 13, 1979. Subsequently, surgery was performed, and Patient B was determined to have an incarcerated right femoral hernia with gangrene, perforation, and generalized peritonitis.

** Patients' names have been coded to protect confidentiality.

Conclusions of Law

Based on the foregoing Findings of Fact, the Commission finds that Respondent has violated Section 15-504(4) of the Medical Practice Act.

Order

Based on the foregoing Findings of Fact and Conclusions of Law, it is this 18th day of June 1985, by a majority vote of those members of the Commission on Medical Discipline considering this case, hereby

ORDERED that the license of the Respondent John Dean Wilson to practice medicine shall be REVOKED, and that the revocation be stayed, and that Respondent be placed on probation upon the performance of the following conditions:

1. That Respondent submit to weekly case review by a supervisor to be obtained by Respondent.

a. The supervisor shall be approved by the Commission and shall be obtained within 30 days of the date of this order.

b. The supervisor shall report to the Commission quarterly. The first report shall be due 30 days from the date that the supervisor commences his or her duties under this order.

c. The Commission will entertain a request by Respondent for less frequent case review, and such request must be accompanied by a recommendation by the supervisor that weekly review is no longer necessary.

2. Respondent shall remain free of alcohol and Respondent shall establish a contract with the Physicians' Rehabilitation Committee of Med Chi and abide by the conditions of that contract.

3. Respondent shall refrain from private practice without the approval of the Commission.

Upon expiration of the three years from the date of this Order, the Respondent may petition the Commission for reinstatement of his license, and it is further

ORDERED that in the event that the Commission determines, after notice to Respondent and an opportunity to be heard, that Respondent has not complied with the conditions set forth herein, it may revoke the stay and impose any disciplinary sanction it deems appropriate.

HILARY T. O'HERLIHY **MD, Chairman**
Commission on Medical Discipline of Maryland

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Tables are to be typed on separate sheets of paper, numbered, and have a brief descriptive title. The Editor reserves the right to edit tables. Be sure that statistics are consistent in both tables and text.

References are limited to those citations noted in the text. References are to be typed double-spaced and numbered consecutively as they appear in text. They will be examined critically at the time of review and must be kept to a minimum. The number of references is generally limited to 20 in major contributions and fewer in shorter articles. Exceptions may be made if appropriate in the opinion of the reviewing editor. Personal communications and unpublished data should not be included. The following are necessary: names of all authors, complete title of article cited (lower case), name of journal abbreviated according to *Index Medicus*, volume number, first and last page numbers, and year of publication. For more extenisve information about preparing medical articles for publication, the editors suggest the International Committee of Medical Journal Editors: Uniform requirements for manuscripts submitted to biomedical journals. The complete document is available in the June 1982 issue of the *Annals of Internal Medicine*.

Illustrations are material that cannot be set in type. Photographic material must be submitted as high-contrast, glossy prints. Drawings and graphs must be done professionally in india ink on high-grade white drawing paper. *Omit illustrations that do not increase understanding of text, and limit them to a reasonable number.* Four or fewer illustrations should be adequate for a manuscript of 4 to 5 typed pages. Legends are to be typed on a separate sheet of paper. Type on a gummed label and affix to the back of each illustration: figure number, title of manuscript, name of senior author, and arrow indicating top. Legends for illustrations should be typed on a separate page with numbers corresponding to those on the photographs and drawings. *Cost of printing color* photographs must be borne by the author.

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Statements made or opinions expressed by any contributor in any article or feature published in the *Journal* are the sole responsibility of the author.

Doctors Take Note

The Johns Hopkins Medical Institution

All courses at the Turner Auditorium Building unless otherwise indicated. Sponsored Continued Education Activities for 1985–86. Info: Office of Continuing Education, 720 Rutland Ave., Turner Auditorium, Baltimore, MD 21205 (301-955-5880).

Thursday until Dec 12 Reproductive Endocrinology Lecture Series, Woodruff Lecture Hall, Houck Bldg., Room 240A. 1 AMA Cat I credit, 1 Cognate/session, American College of Obstetricians and Gynecologists. Info: J. Ryan 301-955-6046.

Feb 24–25 Applied Ethics: Caring for the Mentally Impaired Elderly. Fee: two days $150; one day $100. Appropriate credits applied for. Info: P. Macedonia 301-955-6085.

Apr 7–12 Pediatric Trends 1986. Fee: $500; 45 AMA and 45 PREP credits. Info. Course Coordinator 301-955-5880.

Apr 14–15 *In Vitro* Toxicology—Approaches to Validation. Fee: $225 before Mar 1, $275 thereafter; 15 AMA Cat I credits and 1.5 CEU pending. Info: J. Ryan 301-955-6046.

Apr 28–30 Interventional Radiology and DSA. Fee: $325 physicians; $175 residents, nurses, technologists; 25 AMA Cat I credits; ECE by ASRT. Info: C. Kearney 301-955-3168.

The Department of Radiology and Radiological Science offers several courses in abdominal and obstetrical ultrasound: Courses scheduled 1/6/86–12/8/86. Info: J. Mosmiller 301-955-8450.

Basic Practicum Jan 6–10, Mar 10–14, June 9–13, Sep 8–12, Nov 17–21. Fee: $460; 40 AMA Cat I credits.

Advanced Obstetrics & Gynecology Feb 26–28, Apr 23–25, Sep 4–6, Nov 5–7. Fee: $325, 24 AMA Cat I credits.

Visiting Physicians offered weekly throughout the year for experience in the lab and participation in read-in sessions. By appointment. Fee: $460; 40 AMA Cat I credits.

Advanced Practicum in Ultrasound May 19–23, Sep 22–26, Dec 8–12. Fee: $460, 40 AMA Cat I credits.

Continuously throughout the year. One-week Microsurgery Training Course. Basic techniques and principles, individualized instruction, and practice sessions. Fee: $1,200; 40 AMA Cat I credits. Info: Prog. Coord. 301-955-3169.

The Johns Hopkins Medical Ground Rounds. Accredited audiovisual subscription program for the practicing physician. 40 AMA Cat I credits/year. Write to the Johns Hopkins University School of Medicine, Office of Continuing Education, 720 Rutland Ave., Baltimore, MD 21205 (301-955-3988).

Diagnostic Cytopathology for Pathologists, 1986 Postgraduate Institute: February to May 1986, subspecialty residency in Clinical Cytopathology, compressed into 152 AMA Cat I credits in two courses, both of which must be taken:

Feb—Apr—Home Study Course A, personal reading and microscopic study in own laboratory and

Apr 28—May 9—In-residence Course B, concentrated lecture series, laboratory study, and clinical experience at the Johns Hopkins Medical Institutions, Baltimore, MD, USA.

Designed solely for pathologists who are certified (or qualified for certification) by the American Board of Pathology or its international equivalent, this institute is an intensive refresher in all aspects of Clinical Cytopathology with time devoted to newer developments and techniques, special problems, and recent applications including *immunodiagnosis* and *needle aspiration.* Loan slide set with texts (Course A) will be sent each participant within the US and Canada for home study during Feb through Apr before Course B in Baltimore, Apr 28–May 9. Participants *outside* the US and Canada must make arrangements to study Course A before Course B. *The entire course is given in English.*

Application and completed preregistration is advised ASAP: completed preregistration must be done before March 28, 1986, unless by special arrangement. Info: John K. Frost MD, 604 Pathology Bldg, The Johns Hopkins Hospital, Baltimore, MD 21205, USA

• • •

University of Maryland School of Medicine

CME Courses: For each course additional information may be obtained by contacting Program of Continuing Education, University of Maryland School of Medicine, Room 300, MSTF, 10 South Pine St., Baltimore, MD 21201 (301-528-3956).

Nov 21–23 Symposium on Obstetrics and Gynecology: An Up-to-Date Postgraduate Course. Baltimore Plaza Hotel. Fee: $150; 13 AMA Cat I credits.

Nov 23 Alzheimer's, Dementia and Related Disorders: Diagnosis and Medical Treatment. Hyatt Regency, Baltimore. Fee: TBA; 6 AMA Cat I credits.

Dec 6 Hypertension Symposium. UMAB Campus. Fee: TBA, 6 AMA Cat I credits.

Dec 6–7 Office Management of the Injured Patient. Baltimore Plaza Hotel. Fee: $125, 10 AMA Cat I credits.

Jan 24–26 Current Controversies and Techniques in Congenital Heart Surgery. Baltimore Convention Center. Fee: $225, 12.5 AMA Cat I credits.

Oct thru May—Visiting Practitioner Preceptorship Program. Acceptance on approval of Departments. Hour-for-hour AMA Cat I credit.

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Sep thru Jun—Visiting Professor Program—

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Miscellaneous Meetings

Nov 20 The Challenge of Hypertension Compliance: How to Increase Patient Adherence, CME topic presented by the Center for Health Education, Inc., to be held at Southern Maryland Hospital Center 12:30–2:00 p.m. (lunch), no fee, 1.5 AMA Cat I credits. Info: J. Mannion 301-837-2705.

Nov 20–22 8th National Trauma Symposium—Making a Difference, Sheraton Inner Harbor, Baltimore. Info: P. McAllister 301-528-2399.

Nov 22–23 Maryland Scientific Meeting of the American College of Physicians in Annapolis. Info: J.H. Mulholland MD 301-554-2284.

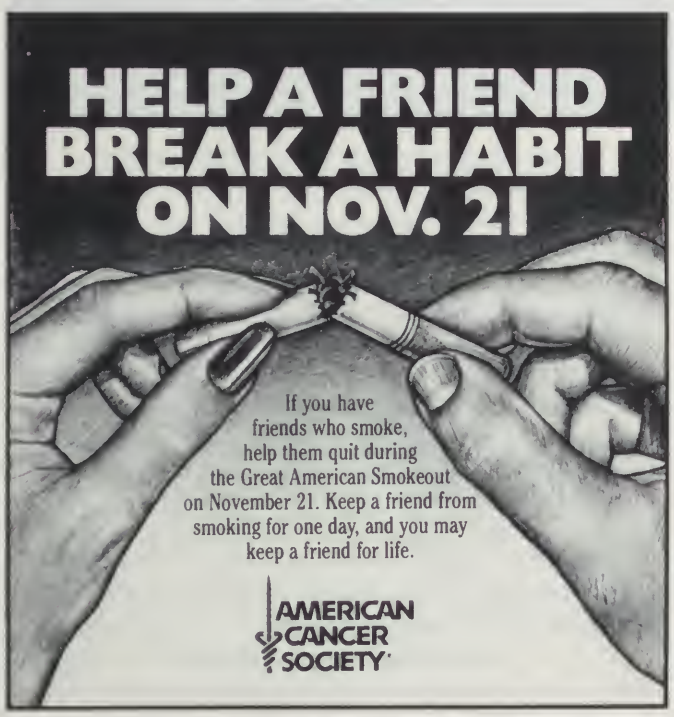
Nov 26 The Adolescent Female Drug Addict, 3–5 p.m. at Changing Point, Ellicott City, MD. 2 AMA Cat I credits, 2 AFP elective credits. Info: 301-465-9500; 202-621-4771.

Nov 26 Artificial Heart Implant, William DeVries MD. Maryland General Hospital's C.W. Stewart Memorial Lecture. Info: 301-225-8790.

Dec 4–6 Recent Advances in Clinical Medicine. Info: Chairman, Department of Medicine, Box 466, Charlottesville, VA 22908 (804-924-2042).

Dec 17 Evaluating for Alcoholism, 3–5 p.m. at Changing Point, Ellicott City, MD. 2 AMA Cat I credits, 2 AFP elective credits. Info: 301-465-9500; 202-621-4771.

This space contributed as a public service.



March 5, 12, 19 Psychoanalytic Perspectives on Ulcerative Colitis at the Baltimore–DC Psychoanalytic Institute, 821 N. Charles St., Baltimore. First in a series of presentations on Classical Psychosomatic Disorders. 8–9:30 p.m.; 4.5 AMA Cat I credits for program. Mar 5: Review of Important Literature; Mar 12: Implications for Medical Management; Mar 19: Participants opportunity to discuss cases. Info/registration 301-727-1740.

May 8–10 Alumni Crab Feast, University of Maryland School of Medicine, 7–10 p.m. Students Common, MSTF. Info: J. Thompson 301-528-7454.

May 10 Alumni Reception and Dinner Dance, at the Sheraton Inner Harbor, University of Maryland School of Medicine. Info: J. Thompson 301-528-7454.

May 27–31 Fifteenth Annual SCCM Educational and Scientific Symposium, Washington, DC. Fee: Nonmember physicians $375, nurses and therapists $270, member physicians $275, nurses and therapists $225; approx 40 Cat I credits. Info: T. Schultz 714-870-5243.

• • •

Taylor Manor Hospital CME Lectures

All lectures at 3 p.m. in the Psychiatric Center at Taylor Manor Hospital, Ellicott City, MD unless otherwise indicated. Info: Taylor Manor Hospital, College Ave., Ellicott City, MD 21043 (301-465-3322).

Dec 4 New Female Adult Developmental Theory: A Critique of the State of the Art

Future Med-Chi Meetings

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1986 Semiannual
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- Internal Medicine (2)
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Gucci 1036
Gundry Hospital 1061
Hidden Brook Treatment Center 1048
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Intracare Corporation 1056
JBA Leasing 1115
Kipp & Son 1046
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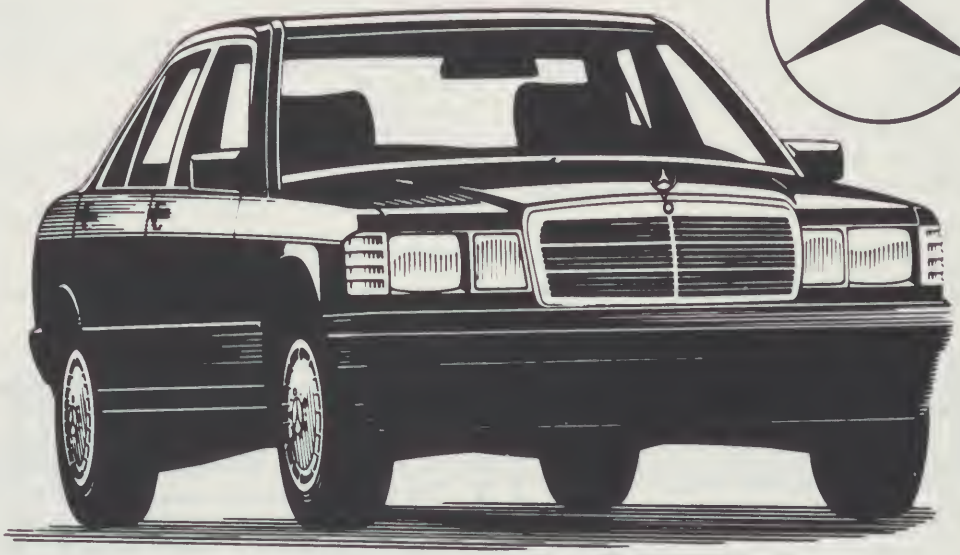
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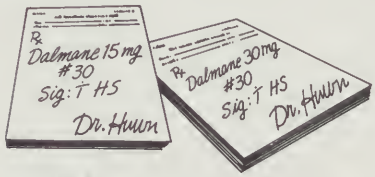
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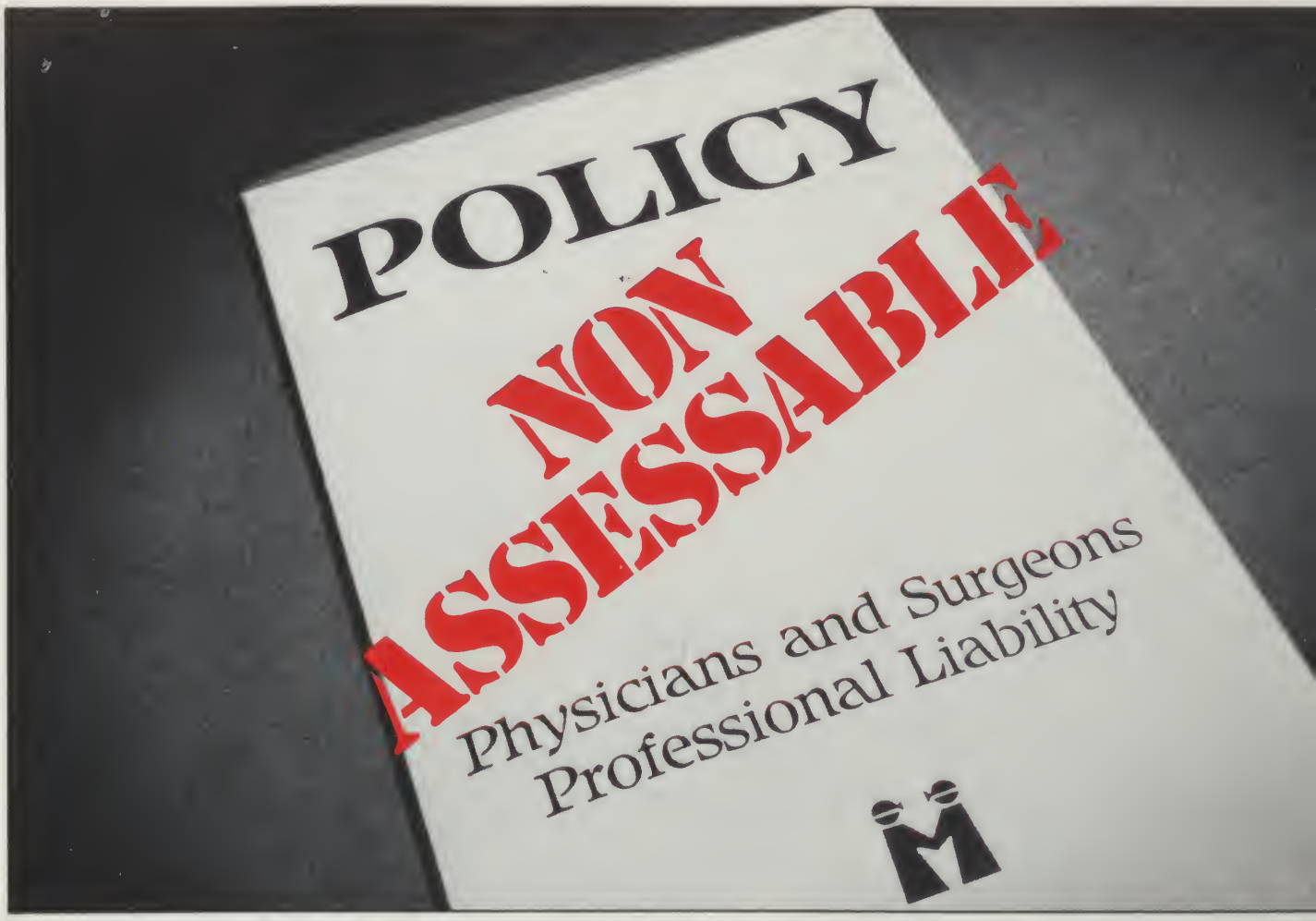
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Members in the News 1209
Doctors Take Note 1210
Classified Ads 1215
1985 Index 1216
Advertisers' Index 1223

ARTICLES

Editorial: Reporting Revisited—James P.G. Flynn MD 1167
The Viral Hepatitis Surveillance System in the State of Maryland—Thomas P. Gross MD, Christina P. Lazar MD, and Ebenezer Israel MD 1169
Cost Analysis of AIDS Cases in Maryland—Randy Berger MD 1173
Comprehensive Rehabilitation of Head Injured Adults—John D. Ranseen PhD 1176
MIEMSS: Topics of Interest—Center for Living: Trauma Aftercare and Outcomes—Margaret M. Epperson-Sebour MSW and Elaine W. Rifkin MSW 1187

DEPARTMENTS

The Impaired Physician 1136
Auxiliary 1138
Today's Psychiatry 1139
Disease Control and Epidemiology Newsletter 1149
HBP Commentary 1154
Maryland Oncology Newsletter 1157
Baltimore City Medical Society 1158
One Minute with Diabetes 1159
Your Medical Faculty at Work 1160
The Library Page 1161
Insurance Monitor 1162

TRANSACTIONS

Semiannual Session—Minutes of House of Delegates 1194
Commission on Medical Discipline 1199
Delegates to the AMA House of Delegates 1201
MMPAC Board of Directors 1205

On the cover: The seal of the Medical and Chirurgical Faculty of the State of Maryland. The Greek inscription reads, in context, "When the need is for the dressing of wounds and the stilling of pain, one physician or surgeon is *of more value* than an army of *other men*." Iliad (Book 11, line 514), Homer, translated by Med-Chi's Librarian, J. Jensen.

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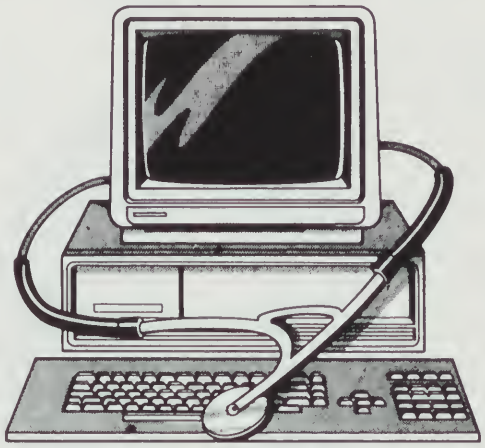
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The Impaired Physician

Nobody Knows

On numerous occasions John Davis MD, Director of the Resource Group and Assistant Professor in the Department of Family Medicine at the University of Maryland School of Medicine, has stated that there are three falsehoods every practicing alcoholic believes to be true:

Nobody knows
I've got it under control
I can handle it by myself

At some point in the progression of alcoholism or other drug dependency, the first delusion is true: nobody knows. This delusion persists even as it begins to shatter. The nagging suspicion that there may be a problem leads to redoubled efforts to keep the drinking or drug use under control, which perpetuates the second delusion. Continued drug taking feeds an underlying grandiosity that, following some success at control and fueled by redoubled efforts, reinforces the third notion, "I can handle it by myself."

In the early stages of disintegration other people begin to suspect, but they are unsure. They are reluctant to think the worst about a valued friend and colleague, and unless they have benefited from recent education and training in diagnosing chemical dependency, they are apt to be excusably ignorant.

If the first person to become aware and concerned is a spouse, that person is apt to hide his/her concern from others. Generally, spouses willingly participate in early efforts made by the alcoholic to conceal the problem. They also actively share in all three delusions. Many spouses make heroic efforts at substituting their control for the increasingly failing efforts of their alcoholic spouse, the so-called "enabling behavior."

Soon, others begin to know. Some may feel strongly that this is a private matter and therefore will not share their observations, concerns, or uncertainties with others. Thus the alcoholic persists in his/her delusions. If confronted only casually, denial will shield the alcoholic from the impact of the confrontation.

As indicated in an earlier *Maryland Medical Journal* (June 1985, p. 558), "What He Doesn't Know Will Hurt Him," if we are to help we need to become familiar with the signs and symptoms of early chemical dependency, and we need to forcefully communicate our concern to the afflicted person. The latter is best done by persons expert in the process of intervention and confrontation: the Medical Society's Committee on Physician Rehabilitation.

Becoming familiar with the signs and symptoms is not difficult. The first rule in making any diagnosis is to include chemical dependency in the differential. A useful subrule is to remember that chemical dependency is a diagnosis, not an accusation. Chemical dependency is a disease, not a disgrace.

The accompanying table lists common signs that suggest physician impairment due to alcohol or other mood-altering drugs. Should a quick review of this material suggest to you that a valued colleague needs the expert help the Medical Society can provide, your Committee on Physician Rehabilitation can serve such needs. You need only to express your concern to be of help. *Call 539-0872 or the Hot Line 467-4224.* Confidentiality is ensured.

MARTIN J. VALASKE MD
Member, Committee on Physician Rehabilitation

Early Clues of Physician Impairment*

Job history in an applicant
- Inappropriate or overqualifications for the position being sought
- Unexplained gaps in chronologies of periods of training or practice
- Frequent job changes in the same or geographically separate areas
- Changes in training program location, particularly in the absence of a change in specialty
- Vague letters of reference
- An unusual medical history

Hospital activities
- Odor of alcohol on a physician's breath (This finding is so infrequent among social drinking physicians as to make it a highly valuable sign.)
- A decline in carrying out professional responsibilities, record keeping or attendance
- Nonavailability when on call or difficulty being found
- Often late, absent, or ill
- Writing poor or inappropriate orders
- Increasingly irritable with staff and colleagues
- Frequently requests colleagues to cover for him
- Making rounds at unusual or inappropriate hours
- Problems with recent memory
- Overprescribing of mood altering drugs/narcotics for patients
- Many prescriptions for self and family
- Subject of "hospital gossip"
- Self medication for anxiety/depression

Office activities
- Retreat from hospital practice
- Workaholic behavior—incredible energy
- Disorganized work schedule
- Unreasonable behavior and demands on staff
- Patient complaints of inattention, forgetfulness, or inappropriate behavior or remarks
- Excessive inventory of drugs for office use
- Frequent office absences
- Increased turnover in office staff
- Decreased workload, shifting work to others
- Slurred speech
- Changes in physician's handwriting
- Development of indecision

Home and family
- Embarrassing behavior excused or explained by family and friends
- Fights, arguments, and violent outbursts
- Children neglected, abused, or in trouble
- Estrangement from nondrinking siblings/parents
- Reckless or grandiose financial ventures
- Personality change
- Sexual problems, extramarital affairs
- Separation or divorce
- Drinking activities come first
- Financial crisis, income tax problems

Friends and community
- Neglected social commitments
- Discontinuance of previous religious affiliations
- Heavy drinking at social/professional functions
- Public behavior embarrassing to others
- Withdrawal and isolation from nondrinking/ nondrugging friends
- Continuing use of alcohol "socially" while simultaneously taking a prescription drug for which continued use of alcohol is ill-advised

Physical health status
- Poor dental health
- Multiple physical complaints and illnesses
- Poor hygiene and poor or inappropriate dress
- Frequent accidents, unexplained bruises, abrasions, or cuts
- Blackouts when drinking
- First seizure in an adult
- Hypertension, arrhythmias, Dupytren's contracture, hepatomegaly
- Gastritis, esophagitis, pancreatitis, hepatitis, enteritis
- Morning vomiting, constipation, obstipation
- Under continuous treatment for "chronic pain"
- "Alcoholic facies" with edema, parotid hypertrophy, facial vascular engorgements
- Inappropriate tremulousness or sweating
- Frequent ER visits and hospitalizations
- Signing out AMA from hospitalization

* Mainly due to chemical dependence including alcoholism

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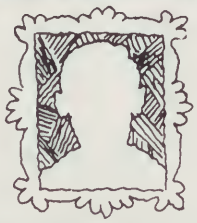
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In 1955, the AMA first called upon the Auxiliary for assistance to support excellence in medical education. The Auxiliary felt an obligation to participate in those programs of the medical profession that improve health and quality of life. Over the past 30 years, fund-raising for the AMA-ERF has been the Auxiliary's sole national philanthropic endeavor.

The State Chairman of AMA-ERF since 1967-68 has been Elizabeth Linhardt (widow of Elmer G. Linhardt MD), a tireless worker and facilitator for AMA-ERF in Maryland. Mrs. Linhardt does not like to take credit for Maryland's success: she believes the Auxiliary and physicians deserve all the credit.

Auxiliary to the Medical and Chirurgical Faculty of the State of Maryland. Mrs. Kathleen S. Karpers, President; Mrs. Helen M. Reichel, Editor.

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Contributing to the AMA-ERF is convenient. Your local Medical Society Auxiliary can assist you. Please help us prepare for the future of medical care in America. Support medical education through the American Medical Association Education and Research Foundation.

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Maryland's Auxiliary customarily divides proceeds from fund-raising efforts between the University of Maryland and the Johns Hopkins Medical Schools; thus our dollars return to work for the cause of medicine in Maryland.

Since 1969 Maryland has been in the National AMA-ERF "Winner's Circle," the recipient of achievement awards in one or more categories, thanks to the generous support of Maryland physicians and the energetic efforts of the Auxiliary.

The Auxiliary's latest award for 1984–85 was second place in the per capita for states category ($45.22). At the state level, first place went to Tennessee with $48.28 per capita, and Connecticut placed third with $41.40 per capita. Harford County placed third in the county per capita category with $128.31. Placing first was District I of Metropolitan Los Angeles (California) and second place went to Boyd County (Kentucky). Other county winners since 1969 have included Baltimore City, Anne Arundel, Baltimore, Charles, Howard, Montgomery, Prince George's, and Talbot counties.

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Today's Psychiatry

Can Suicide be Predicted?

Suicide prevention is a crucial responsibility for all physicians. In addition to fulfilling the obvious life-preserving duty of a medical doctor, one may prevent enormous personal, family, and social consequences by timely action if a reliable prediction can be made.

What is known about suicide predictability?

An attempt at a biologically based prediction has been made recently employing the Dexamethasone Suppression Test (DST). Use of this test seemed reasonable after Bunney *et al.*[1] showed association between serious suicidal behavior and adrenal hyperactivity. Coryell and Schlesser[2] studied 243 patients with unipolar depression: of the five who committed suicide, four were among the 96 with abnormal DST (one had normal DST).

Economic decline in a country long has been known to have significant influence on suicide rates; this was first indicated by Durkheim at the end of the nineteenth century. Recent, sophisticated analyses[3] confirmed this effect noting that 67 percent of unemployment's effect on suicide rates occurs three months after the economic downshift. Modern economists, however, believe that suicide rates do not increase only for the unemployed. Brown[4] noted the unemployment rate in Kansas City between 1971 and 1973 influenced the attitudes and mental health of the population, but he could not determine whether these effects resulted from fear of losing a job, increased tension at work, or actual loss of a job.

A promising approach to prediction of suicide is that of Aaron T. Beck MD, at the University of Pennsylvania. Two hundred seven patients were contacted every six months for five to ten years following discharge from hospital admission due to suicidal ideation.[5] In the course of the study, fourteen patients committed suicide. A score of 10 or more (out of a maximum of 20) on the Hopelessness Scale[5] correctly identified 91 percent of the eventual suicides. Only one suicide scored below 10 (scored 9). Seventy-six patients with a score of 10 or above did not commit suicide.

Contributions from biochemistry, sociology, and psychology point to the importance of developing a low

Hopelessness Scale

If the statement describes your attitude *for the past week, including today*, write down TRUE next to it. If the statement is false for you, write FALSE next to it. You may simply write T for TRUE and F for FALSE. Please be sure to read each sentence.

____ A. I look forward to the future with hope and enthusiasm.
____ B. I might as well give up because there's nothing I can do about making things better for myself.
____ C. When things are going badly, I am helped by knowing that they can't stay that way forever.
____ D. I can't imagine what my life would be like in ten years.
____ E. I have enough time to accomplish the things I most want to do.
____ F. In the future I expect to succeed in what concerns me most.
____ G. My future seems dark to me.
____ H. I happen to be particularly lucky and I expect to get more of the good things in life than the average person.
____ I. I just don't get the breaks, and there's no reason to believe I will in the future.
____ J. My past experiences have prepared me well for my future.
____ K. All I can see ahead of me is unpleasantness rather than pleasantness.
____ L. I don't expect to get what I really want.
____ M. When I look ahead to the future I expect I will be happier than I am now.
____ N. Things just won't work out the way I want them to.
____ O. I have great faith in the future.
____ P. I never get what I want so it's foolish to want anything.
____ Q. It is very unlikely that I will get any real satisfaction in the future.
____ R. The future seems vague and uncertain to me.
____ S. I can look forward to more good times than bad times.
____ T. There's no use in really trying to get something I want because I probably won't get it.

Key: Score 1 for answer "False" to A,C,E,F,H,J,M,O,S.
Score 1 for answer "True" to B,D,G,I,K,L,N,P,Q,R,T.
Add up (maximum 20); 9 or more is high risk of suicide.

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threshold of suspicion for suicidal risk. Obviously, it would be neither practical nor therapeutic to hospitalize all persons with suicidal ideations. Careful evaluation of the personal "safety net" (family and social ties, religious and moral beliefs, health and economic circumstances) is helpful in determining the degree of suicidal risk.

Psychiatric consultation may be indicated in many cases for both medical and legal considerations.

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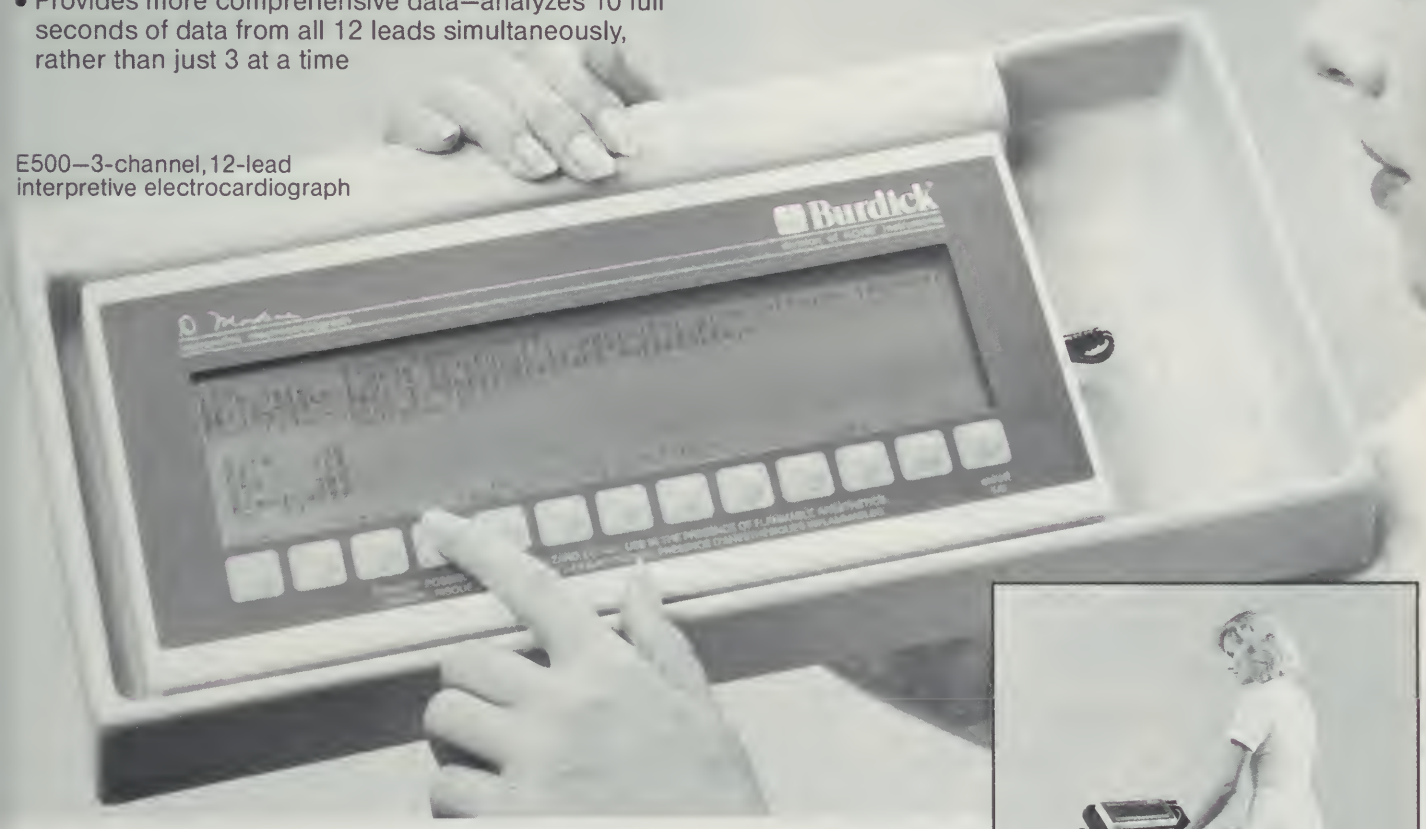
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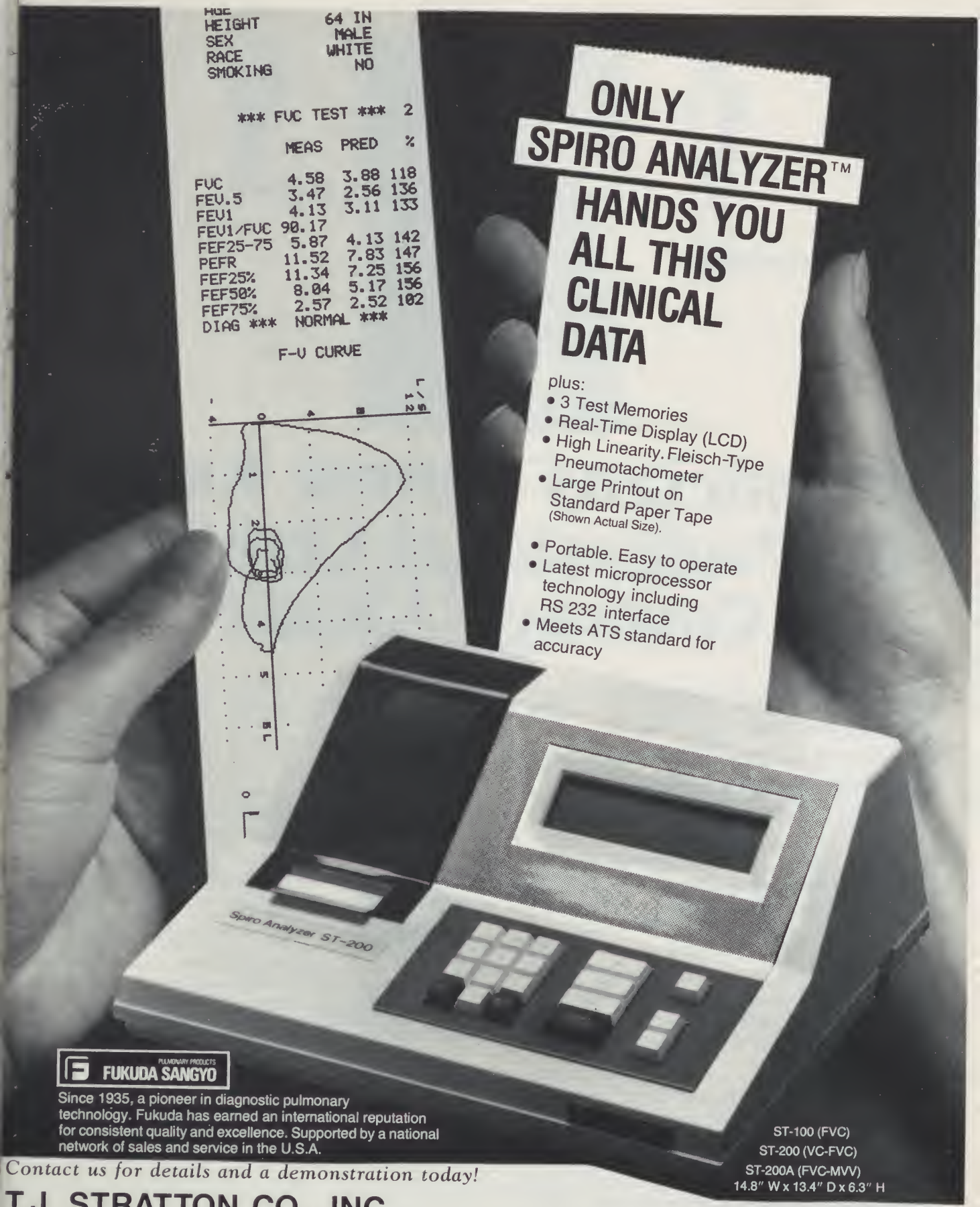
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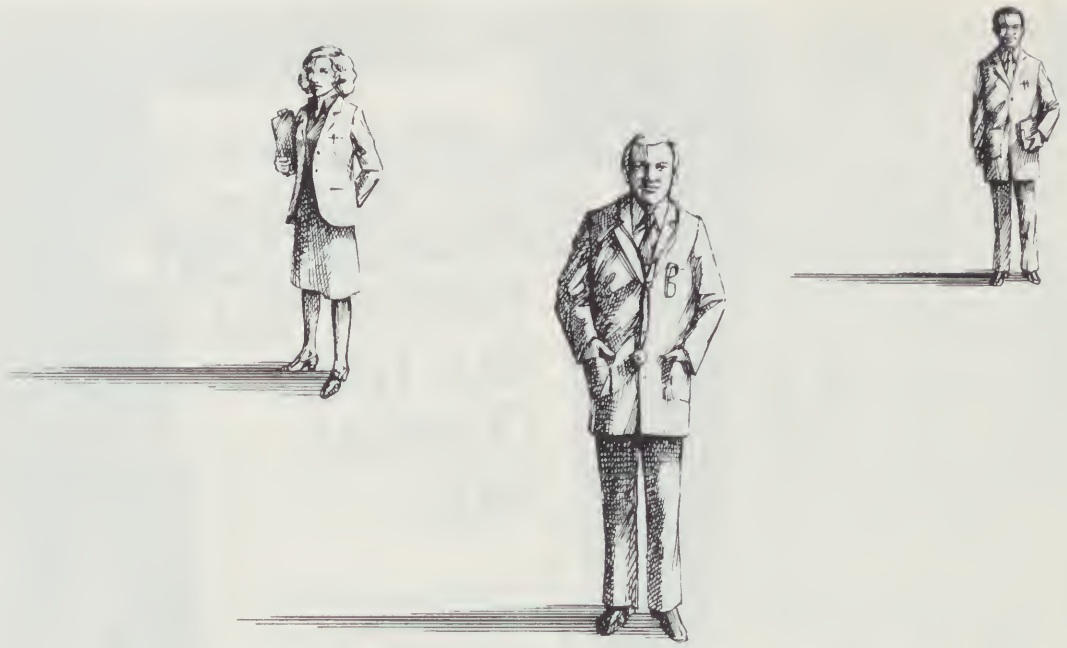
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John Sargeant

1920–1985

John Sargeant, the first Executive Director of the Medical and Chirurgical Faculty of the State of Maryland, died on November 25, 1985. Mr. Sargeant came to Baltimore to serve as executive director in 1958 after five years in a similar post with the Broome County Medical Society in New York State.

One of the first functions in his career with Med-Chi was to oversee the renovation of the Faculty building at 1211 Cathedral Street. More recently he negotiated the acquisition of the adjoining old school building (originally School 49), which is being renovated to expand the Faculty's office space at a cost of almost two million dollars.

From a budget of $153,000 in 1957, the needs of the Faculty now require more than one and a half million dollars. This larger budget provides improved services to about 7,000 members of the Faculty and to the public.

During his tenure, Mr. Sargeant originated many projects that gained legislative approval, including the concept of a separate disciplinary body for physicians, in which the profession itself plays a significant part; a Faculty committee on drugs that oversees appropriate prescribing of drugs by physicians, a measure cited as a model at the National Conference on Drug Abuse held in Washington, DC in 1980.

The formation of the Medical Mutual Liability Insurance Society was a direct result of legislative efforts during the professional liability crisis in 1975. More recently Mr. Sargeant had been working with professional groups in the current liability crisis. In addition, he served for two 3-year terms on the Board of Review of the Department of Health and Mental Hygiene as well as serving on numerous other state and voluntary agency boards.

Known throughout the state as the "physicians' doctor," he also was well known in his field, speaking nationwide on varied subjects related to his professional career. He was a certified Association Executive, and a member of both the American Society of Medical Executives and the American Society of Association Executives. A founding member of the Maryland Society of Association Executives, he was president in 1973-74. He served on the advisory board to the American Medical Association's Executive Vice-President, as well as the AMA's Public Relations Advisory Committee.

In recognition of a quarter-century with the Med-Chi, a John Sargeant Medical Scholarship Fund was established in 1983.

He was active in the Church of the Good Shepherd in Ruxton, where he served as a lay reader and chalicist.

He is survived by his wife, Jeanne Brennan Sargeant, of Ruxton; two daughters, Hilaire Sargeant and Meredith Harrington; a grandson, Ford Harrington, all of Ruxton; and a brother and sister in Hamilton, Ontario, Canada, of which he was a native and for which country he served as a Royal Canadian Air Force flight lieutenant during World War II. He was a graduate of McMasters University in Canada.

The family suggests memorial contributions be made to the Medical and Chirurgical Faculty Charitable-Educational Fund (Sargeant Memorial), or to the Church of the Good Shepherd.

Executive Director's Newsletter

December 1985

PUBLIC RELATIONS AND PROFESSIONAL LIABILITY CAMPAIGN

The Faculty has contracted with Image Dynamics to produce an advertising campaign to educate the public about Med-Chi and its work and to support the legislative professional liability reform effort. The campaign will include use of billboards, radio advertising, posters, and printed brochures for physicians to use in their office. Funding for the project comes from physicians' voluntary contributions requested at Council's September meeting. The project will be implemented to the extent that funds are available. Malpractice posters and brochures may be ordered by calling Diane Sakwa at 301-539-0872 toll-free in Maryland 1-800-492-1056.

MEDICARE PILOT PROJECT

In the absence of detailed information from Blue Cross/Blue Shield, the Faculty's Council, on November 21, expressed its strong concern that the pilot project assumes responsibility for the Medicare program in Maryland. The Faculty's concern is that the quality of care for federal beneficiaries and access to needed treatment could be jeopardized. Public hearings on the pilot program were held throughout the state at the Governor's request; Faculty members testified.

INSURANCE ALERT

Maryland Insurance Commissioner, Edward J. Muhl, has issued a consumer advisory alert regarding a Dallas, Texas, based company, Physicians Co-operative, which is offering medical malpractice insurance in the State of Maryland through unauthorized insurance carriers, Professional Protection Limited of Zurich, Switzerland, and Bayerasche/Volkveisiern of Munich, Germany. Neither carrier is certified by any state insurance commissioner in the U.S. No guarantees can be made about either company's liquidity, product quality, safety, or ability to satisfy claims. Currently, neither carrier has local agents, claims offices, or legal counsel in Maryland. Physicians entering into these noncertified contracts do so at their own risk. If you have become a member of Physicians Co-operative, purchased the insurance, or been in contact with them, please call Joseph Harrison at the Faculty.

LABORATORY REGULATIONS

New regulations, effective November 18, 1985 require physician group practices (four or more physicians) performing in-house laboratory testing to hire a medical technologist, with proficiency testing and other requirements established under these regulations. Copies of the regulations can be obtained from Judith Theroux at the Faculty office.

MEDICARE FREEZE

Congress has once again extended the deadline for action on the Medicare freeze. The new deadline is December 14, 1985.

AMA HEALTH INSURANCE CLAIM FORM

Physicians now are required to purchase the AMA Health Insurance Claim Form for filing Medicare and Medicaid claims. Medicare carriers have been directed to stop distributing the CFA-1500 form free to physicians, effective October 30, 1985. Previously, the government supplied these forms to Medicare carriers in most states, and carriers made them available to physicians. Under the new regulations, all providers will be required to purchase the AMA Health Insurance Claim Form in single sheets or continuous-feed format from AMA by writing AMA Insurance Form, Book and Pamphlet Fulfillment, P.O. Box 10946, Chicago, IL 60610. Phone 312-280-7168.

In another new regulation, HCFA directed State Medicaid Management Information Systems to use the Health Insurance Claim Form for physicians' services, effective October 1, 1986. This means physicians need to stock only one form for at least three insurers. The form currently is accepted by CHAMPUS, U.S. Dept. of Labor for federal workers' compensation program and black lung program, and many major insurance companies.

PATIENT MEDICATION INSTRUCTION SHEETS

A reminder that PMIs, a tear-off drug information sheet meant to supplement verbal instructions to your patients are still available from AMA. There are PMIs presently available for 81 drugs. Order forms can be obtained from the Med-Chi office.

COMPENDIUM SUPPLEMENTS

The 1985 Supplement to the Faculty's 1984 Compendium of Laws, Regulations, Opinions and Policies Governing the Practice of Medicine in Maryland will be mailed to those physicians who requested a copy of the 1984 Compendium. The 1985 Supplement contains a summary of the new Living Will Statute and the Faculty's newly formulated guidelines concerning Termination of Medical Care. Many Faculty members have not requested a compendium; I urge you to do so now. Please direct your requests to Judith Theroux at the Faculty Building.



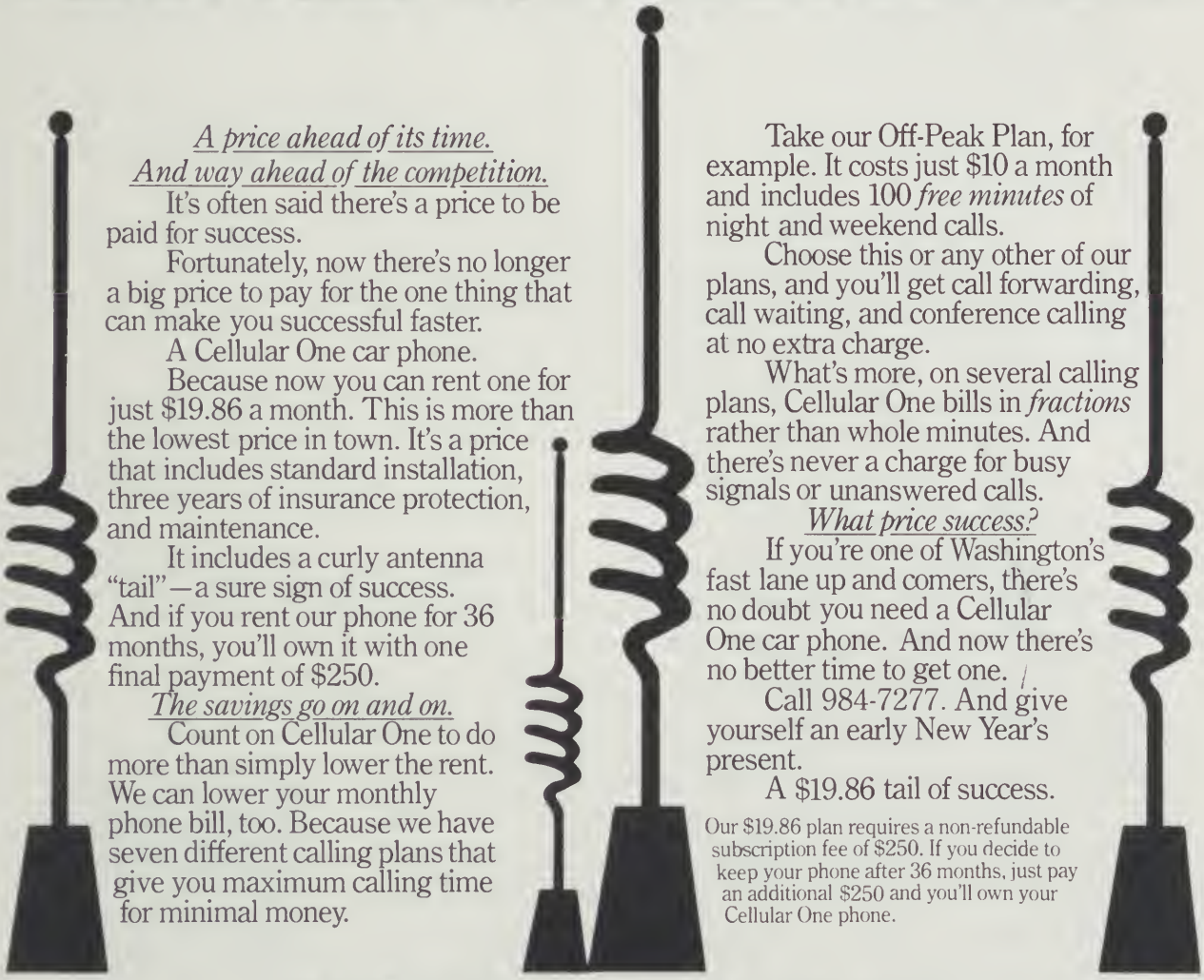
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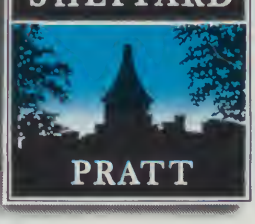
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For some, this means intense confrontation. For others, gentle guidance. Our sensitivity, experience and flexibility enable us to determine the best approach.

If you are sometimes in a position to refer alcoholics or drug abusers to suitable treatment centers, learn more about the individualized approach at Sheppard Pratt.

To get general information about the Sheppard Pratt Substance Abuse Program, or to discuss an individual case, contact: Dr. David Waltos, Admissions Officer, Sheppard and Enoch Pratt Hospital, P.O. Box 6815, Baltimore, Maryland 21204. (301) 823-8200.

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DECEMBER 1985

ENTEROVIRUS SURVEILLANCE - Maryland, 1985

During the first 10 months of 1985, nonpolio enteroviruses were identified in specimens from 25 patients that had been submitted to the Virus Isolation Laboratory, Department of Health and Mental Hygiene. Echovirus 11 was isolated most frequently (6/25), followed by coxsackievirus B2 (5), echovirus 21 (4) and coxsackievirus B4 (3). Other viruses isolated were echovirus 7 (2), coxsackievirus B3 (1) and echoviruses 6, 14, 19 and 30, each one. Thirty-six percent (9/25) of the isolations were from specimens submitted in September.

Of the 21 cases for which age was reported, 76% (16) were less than 1 year old. Seven cases were neonates from whom 5 different virus types were isolated. No significant clustering by date or hospital was noted. Nine cases had the virus isolated from cerebrospinal fluid; 15 from non-CNS sources, primarily feces; and 1 from autopsy specimens. The death occurred in a neonate who had bilateral adrenal hemorrhage and diffuse intravascular coagulation. Echovirus 7 was isolated from the autopsy specimens.

In 1984, the most common isolates were coxsackievirus B2 from 29% (13/45) of all cases; coxsackievirus A9 from 20%; echovirus 9 from 11%, and coxsackievirus B5 from 7%. Coxsackieviruses B2 and B4 and echoviruses 11, 21 and 30 were each isolated in 3 of the last 4 years, but no single type was isolated every year. The pattern of virus isolations in one year is not a predictor of the following year's experience. For example, echovirus 11, the most common isolate this year, was also the most common isolate in 1983 (14/47), but it was not isolated at all in 1984.

AMPICILLIN RESISTANCE IN HAEMOPHILUS INFLUENZAE MENINGITIS Maryland - 1985

In the first 10 months of 1985, 76 cases of bacterial meningitis caused by Haemophilus influenzae have been reported to the Office of Disease Control and Epidemiology by physicians, hospitals, medical laboratories and local health departments. Fifty-six cases (74%) were less than 2 years old; 17 (22%) were 2-5 years old; and 3 (4%) were greater than 5 years old.

Isolates of H. influenzae were type b in 43 cases; type c in 1 case; untypable in 1 case; and type not reported in 31 cases. Ampicillin resistant H. influenzae was reported in 29% (11/38) of the cases for which the resistance status was known.

Ninety-three (93) and 114 cases of H. influenzae meningitis were reported in 1983 and 1984, respectively. Resistance to ampicillin was reported for 25% (18/72) of the isolates in 1983 and 35% (30/86) in 1984. The differences in the annual rates of ampicillin resistance are not statistically significant. No chloramphenicol resistant isolates of H. influenzae were reported in any year.

Data from Centers for Disease Control's (CDC) passive surveillance system for bacterial meningitis showed a trend of increasing prevalence of ampicillin resistant H. influenzae from 1978-1982 (1). During that period, 17% of Maryland's H. influenzae isolates were ampicillin resistant.

Maryland continues to experience an average of 100 cases of H. influenzae meningitis each year. Ampicillin resistant strains of H. influenzae have become more prevalent. Maryland's surveillance program for bacterial meningitis will continue to assess and report on the changing pattern of Haemophilus influenzae's antibiotic sensitivity.

Submitted by David H. Trump, M.D., M.P.H., Resident, Johns Hopkins School of Hygiene and Public Health.

Reference:

1. Centers for Disease Control. Ampicillin and chloramphenicol resistance in systemic Haemophilus influenzae disease. MMWR 1984;33:35-37.

ESTROGEN PLUS A PROGESTIN FOR PREVENTION OF POSTMENOPAUSAL OSTEOPOROSIS

Prophylactic treatment with estrogens can decrease the risk of postmenopausal osteoporosis, but also increases the incidence of endometrial cancer (Medical Letter, 18:99, 1976). Recently, some physicians have recommended giving postmenopausal women a progestin in addition to estrogen, in order to avoid increasing the risk of endometrial cancer (RD Gambrell, Jr., Curr Probl Obstet Gynecol, 7:1, Oct. 1984). Some women continue to produce endogenous estrogens after menopause and do not need estrogen therapy; pap smears can be used to evaluate production of endogenous estrogens.

EFFECTIVENESS OF ESTROGEN--Several controlled trials have shown that estrogen prophylaxis prevents osteoporosis, decreases vertebral and other fractures, and prevents further loss of heights. A long-term prospective study of estrogens in 1,000 women treated for about 15 years found that wrist fractures decreased by 70% from the expected rate and no hip fractures occurred in treated women (JC Burch et al, in PA Van Keep et al, eds, Consensus on Menopause Research, Lancaster, England:MTP Press, 1976, p 164). Patients treated with conjugated estrogens,

fluoride and calcium in another trial had fewer fractures than those treated with placebo, calcium alone, or calcium plus fluoride (BL Riggs et al, N Engl J Med, 306:446, 1982). In a retrospective case-control study, 245 long-term estrogen users followed for an average of 17.6 years had 50% fewer osteoporotic fractures than matched controls (B Ettinger et al, Ann Intern Med 102:319, 1985). A US National Institutes of Health Consensus Development Conference recently concluded that giving estrogen and supplemental calcium is the best way to prevent osteoporosis (WA Peck et al, JAMA 252:799, 1984).

ADDING A PROGESTIN--Unopposed estrogen therapy promotes development of endometrial hyperplasia and cancer, primarily because of incomplete shedding of the endometrium. Adding a progestin ensures more complete sloughing of the endometrium, leaving fewer glands for continued proliferation (MI Whitehead et al, N Engl J Med, 305:1599, 1981). In one study, which was not-well controlled, low dosage estrogen was associated with a 7% incidence of endometrial hyperplasia, compared to a 15% incidence with high-dosage estrogen. When progestins were given five to 10 days per month in addition to either high-or-low dosage estrogens, the incidence of hyperplasia was 2%; patients taking progestins for 13 days each month had no endometrial hyperplasia (MH Thom et al, Lancet, 2:455, 1979).

CLINICAL USE--A 10 year double-blind trial compared bone density in 84 hospitalized patients receiving conjugated estrogens (2.5 mg daily) and medroxyprogesterone acetate (10 mg daily for seven days of each month) with that in 84 women receiving placebo. Bone density increased with treatment begun less than three years after last menses and decreased with placebo. No endometrial cancer was diagnosed in the patients taking both estrogen and a progestin for 10 years; one endometrial cancer occurred among those taking placebo (LE Nachtigall et al, Obstet Gynecol, 53:277, 1979; 54:74, 1979). A retrospective study found no endometrial cancers in 72 women taking both estrogen and a progestin (10 mg daily of medroxyprogesterone acetate for seven to 10 days per cycle) for at least five years; 11 cancers developed in 127 patients treated with estrogen alone (CB Hammond et al, Am J Obstet Gyncecol, 133:537, 1979). In another study, the incidence of endometrial cancer in estrogen-progestin users (eight in 11,753 patient-years) was lower than in women taking estrogen alone (10 in 2,434 patient-years) and also lower than in non-hormone users (nine in 3,484 patient-years) (RD Gambrell Jr, South Med J, 77:1509, 1984).

ADVERSE EFFECTS--One major disadvantage of adding cyclic progestin to estrogen replacement therapy is the return of light to moderate menstrual periods. Progestins in oral contraceptives have been associated with undesirable changes in blood lipids and an increased risk of cardiovascular disease (Medical Letter, 25:69, 1983).

CONCLUSION--Limited clinical studies suggest that concurrent use of estrogen plus a progestin might decrease postmenopausal osteoporosis without increasing the risk of endometrial cancer, but large-scale, long-term, well-controlled studies of the

effectiveness and safety of such regimens are not available.

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SURVEILLANCE OF ADVERSE DRUG REACTIONS IN MARYLAND

The Food and Drug Administration has awarded a contract to the Maryland Department of Health and Mental Hygiene to conduct a pilot study of adverse drug reaction surveillance and reporting by practicing physicians. This project, conducted in collaboration with the Johns Hopkins Pharmacoepidemiology Unit and the Center for Health Education, Inc., will attempt to determine the factors which inhibit physician reporting and implement methods to promote reporting. While over 36,000 adverse drug reports are received annually by the FDA, only 4,000 come directly from prescribing physicians. Proportionately, physician reports involve more serious and unexpected reactions than those from manufacturers and, therefore, represent an important source of signals in drug safety surveillance. If you require more information, please contact Dr. Audrey Rogers (Tel. 955-5559).

MARYLAND AIDS CASES BY YEAR

	CASES	DEATHS	STATUS UNKNOWN
1979-81	4	4	0
1982	6	6	0
1983	25	23	1
1984	67	49	0
1985 YTD (Dec. 1)	144	63	0
TOTAL	246	145	1

Centers for Disease Control National Statistics
as of 12/2/85

Reported Cases 15,172 Deaths 7,777

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HBP Commentary

Ambulatory Blood Pressure Monitoring: Limitations and Clinical Uses

R. PATTERSON RUSSELL MD and CAROL LEWIS ScD

Ambulatory blood pressure monitoring has potential value in the prognosis, diagnosis, and therapy of hypertensive patients. However, the value of this technique as a research tool should not lead to its use as a presumed panacea in clinical practice; rather, the physician may want to define subsets of patients for whom this type of diagnostic work-up is most appropriate.

Russell is Associate Professor, Johns Hopkins School of Medicine; Lewis is Executive Director of the Maryland High Blood Pressure Commission.

Having provided background information concerning ambulatory blood pressure monitoring (ABPM) and its ability to predict target organ damage in the November issue, we now deal with the limitation and clinical uses of ABPM.

Limitations

Direct intra-arterial measurement provides precise data but remains a specialized procedure for use in research centers since it requires substantial resources of equipment, experienced personnel, and careful observation of the subject. Although complications are infrequent, moderate morbidity, including localized paresis due to median nerve palsy, has been reported. Most studies using direct arterial measurements are performed in Great Britain, whereas ABPM in North America has involved use primarily of noninvasive BP measurement methods.

The currently available noninvasive recorders are based on the auscultatory of Korotkoff sound technique in combination with oscillometry in some instruments. Therefore these recorders have the same *physiological* limitations common to all sphygmomanometric techniques, but they do have the advantage of avoiding such problems as observer bias and the "white-coat" effect.

Recorders today may be categorized as semiautomatic or fully automatic. The former requires the patient to inflate the cuff manually and have the advantage of being less bulky, but readings cannot be obtained while the patient is asleep. While the latter require a battery operated pump (and are thus bulkier), they require no active involvement by the patient and can be preset to take readings at regular intervals.

A serious limitation to the clinical relevance of ABPM is the lack of clearly defined *normal values* against which recordings from patients can be judged. The conventional definition of hypertension, on which we base our assessment of risk and the need for treatment, is based on clinical measurements. Measurements obtained from ABPM provide us with additional dimensions, namely the variation of BP with time and with normal daily activities. Thus the correlation of the patients' activities at the time of the BP measurement is of utmost importance to avoid miscategorization. In addition, the daily range and variability of blood pressure in normal subjects must be established through waking and sleeping cycles to make clinical sense of ABPM data for hypertensive patients; such research is beginning to be reported.

Another problem lies in making clinical sense out of abundant data. Data provided by 24-hour ambulatory blood pressure methods far exceed the number of data points available using office blood pressure methods. In the direct arterial blood pressure measurement method, 8,000 to 12,000 blood pressure measurements are recorded per 24-hour period. In the noninvasive methods approximately 48 to 192 blood pressure readings are available per 24-hour period. A variety of statistical methods have been employed in analysis; some may have serious problems because of the underlying assumption that blood pressure is normally distributed around the mean. Another unanswered question involves whether a 24-hour ambulatory blood pressure recording can be generalized to an individual's usual blood pressure profile.[1]

Sleight pointed out in a recent editorial that all the semiautomatic and automatic machines and "electronic" home sphygmomanometers give reasonably accurate systolic pressure readings but are less reliable for diastolic pressure, which is generally overestimated.[2] None of the recorders work with every patient, and it is necessary to calibrate them against conventional sphygmomanometric measurements. Furthermore, a certain proportion of readings are artifactual, usually due to movement, and must be edited out, a very subjective process.

Use of ABPM in Prognosis, Diagnosis, and Therapy

Ambulatory blood pressure recording is valuable in prognosis, diagnosis, and therapy. Since blood pressure is a continuous variable in the population, and since risk is proportional to the level of blood pressure, it is sometimes a problem to decide which patients are sufficiently at risk of developing future cardiovascular morbid events to warrant treatment. This is especially true in the range of the blood pressure spectrum gen-

HBP Commentary is contributed by the Maryland High Blood Pressure Commission, 201 W. Preston St., Baltimore, MD 21201 (301-225-5891). Editors: R. Patterson Russell MD, Past Chairman; Donald O. Fedder PharmBS, DrPH, Chairman; and Carol Lewis MPH, ScD, Executive Director.

erally called "mild hypertension" (DBP 90 to 104 mmHg). One diagnostic objective of 24-hour ambulatory recording has been to identify, within a group of "mild hypertensives," those subjects who need not and those who should be treated with medication. Perloff and Sokolow have collected extensive data relating ambulatory blood pressures to prognosis. They reviewed the course of 1,076 patients with essential hypertension. Although their subjects did not represent a probability sample, their data are nevertheless impressive and allowed them to distinguish between high- and low-risk subgroups at risk for first cardiovascular events, whereas office blood pressures of the same patients did not allow such distinction.[3] The predictive power of ABPM was greatest in those persons with milder hypertension.

Pickering *et al.* recorded blood pressures taken every fifteen minutes using a noninvasive ambulatory blood pressure recorder during 24 hours with three groups of subjects: 25 subjects with normal blood pressure, 25 with borderline hypertension, and 25 with established hypertension.[4] Readings were analyzed for four situations: physicians' offices, work, home, and sleep. Treadmill exercise tests were performed on a separate occasion. The 24-hour recording in all three groups showed the highest blood pressures at work and the lowest during sleep. Situational blood pressure changes were generally similar in each group, but the hypertensive groups differed from normal subjects in that they showed consistently higher blood pressures in doctors' offices than at home, whereas normal subjects showed little difference. During exercise the hypertensive group showed a rise in systolic pressure similar to that of normal subjects. Pressures recorded in physicians' offices gave good predictions of the average 24-hour pressure in normal and established hypertensive subjects but *not* in the borderline group. Although this work needs to be replicated, it appears that 24-hour monitoring may be of particular value in deciding on the need for treatment for "borderline" patients.

ABPM has been used to determine 24-hour efficacy of drug therapy. This may help determine frequency of dosage (important because of the influence it has on compliance) and amount of dosage (important because of possible side effects).

Problems involving reliability of the instruments, analysis of abundant data, interpretation of the data, possible doubt that 24-hour blood pressure samples can be generalized, and cost suggest prudent use in clinical practice. The physician may want to define subsets of patients for whom this type of diagnostic work-up is most appropriate rather than routinely prescribe it. The value of ABPM as a research tool, including expansion of our understanding about blood pressure variability and the effects of daily living, should not lead to its use as a presumed panacea in the diagnosis and treatment of the individual.

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*JAMA. Volume 248, No. 3, pages 336-339
Yearbook of Medicine. 1983, pages 66-67
Pediatric Infectious Disease.Volume 3, No. 6, pages 514-517

Maryland Oncology Newsletter

New Drug Development Program

There are certain limitations on the available chemotherapeutic agents that are effective in a variety of human cancers. Even with drugs considered effective in some cancers, the response rates are low, usually in the range of 20 ± 5 percent. This includes partial as well as complete responders. In addition, the duration of response is low, ranging from two to five months. It is clear that new agents must be sought for better cancer control.

New drugs have shown some activity in animal tumor models during pre-clinical investigations and have become available for clinical trials. Each new agent has to undergo very careful evaluation and scrutiny in controlled clinical settings. All new chemotherapeutic agents are evaluated clinically in three phases, with specific aims in each phase.

Phase I clinical trials are pharmacological studies to identify the most effective dose of the drug, method of administration, and side effects, that is, toxicity. Candidates for such trials are patients with advanced stages, metastatic, or unresectable tumors that failed to respond to standard therapy. While the main objectives are being met, certain tumor responses also should be noted and correlated to dosage. The end point for Phase I studies is to establish the most effective dose of the drug and its toxicity in humans.

Phase II clinical trials seek to identify certain tumors that respond to specific new agents. At least 30 tumor patients in each of the main five signal categories (gastrointestinal, lung, gynecological/breast, head and neck, sarcoma/melanoma) are treated to identify their response rates. This includes percent of responders and duration of response. If the new agent is found effective in certain tumors, it then can be considered by the Food and Drug Administration (FDA) for approval and marketing. In the meantime it can be studied further in Phase III clinical trials.

Phase III trials seek the best use of the agent, comparing this new drug to an established agent to find out which is more effective. Another approach is to administer the new drug in addition to a standard one in an attempt to improve on response rates and duration of response. Occasionally, such clinical trials include Phase I and II in one study to obtain fast results in tumors that are not common or are known to be resistant to other therapeutic programs.

The National Cancer Institute (NCI), one of the institutes of the National Institutes of Health (NIH), has sponsored a New Drug Development Program and given grants to four centers: Cancer Memorial-Sloan Kettering, M.D. Anderson, Mayo Clinic, and University of Maryland Cancer Center (UMCC). The program seeks to identify effective new chemotherapeutic agents for patients with malignancies. UMCC in Baltimore is looking for patients with a variety of cancers to be treated with these new agents. Patients can be treated and followed at UMCC or treated at UMCC then followed by their referring physicians. A list of those studies follows.

If you have questions, please call or write the Surgical Oncology Program at the University of Maryland Medical System, Room N13E02, Baltimore, Maryland 21201 (301-528-5224).

Drug Development Studies

Protocal Numbers NCI	Protocal Numbers UMCC	Title
T83-0872	U8029-01	A Phase I-II Trial of AZQ (NSC 182986) In Patients with Recurrent Primary or Metastatic Brain Tumors
T85-0006	U8422-00	Randomized Study of Methotrexate Versus Methotrexate Plus Carboplatin (NSC 421240) in Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck
T85-0042	U8506	Combined Treatment of CBDCA and Radiotherapy In the Primary Management of Patients with Advanced Locoregional Squamous Cell Carcinomas of the Head and Neck
T84-0210	U8327-01	Phase II Trial of 4'Deoxydoxorubicin in the Treatment of Patients with Unresectable or Recurrent Non-Small Cell Lung Cancer
T83-1076	U8313	A Phase II Study of N-Methylformamide (NMF, NSC3051) in Advanced or Recurrent Colorectal Cancer
T83-1081	U8308	A Phase II Study on N-Methylformamide (NMF, NSC3051) in Advanced Renal Cell Carcinoma
T83-1304	U8324-02	A Phase II Study of Carboplatin, Platinum Diammine (1,1-Cyclobutane-Dicarboxylate(2)-0,0[1]) (CBDCA NSC 241240) in Patients with Advanced Renal Cell Carcinoma
W83-146	U8234-02	A Phase II Trial of Mitoxantrone (NSC 301739) in Advanced Prostate Cancer
W83-79	U8226-01	A Phase II Trial of Carboplatin, Platinum Diammine (1,1-Cyclobutane-Dicarboxylate (2)-0,0[1])(CBDCA NSC 241240) in Patients with Advanced Gynecologic Malignancies
T83-1303	U8322-00	A Phase II Study of High Dose BCNU Followed by High Dose Melphalan in Combination with Vincristine in the Treatment of Metatastic Malignant Melanoma
W82-1275	U8224-00	A Phase I-II Trial of AZQ (NSC182986) in Patients with Refractory Adult Acute Leukemia

For further information and/or referral, please feel free to call or write David VanEcho MD or Mario Eisenberger MD, The University of Maryland Cancer Center at the University of Maryland Medical System, Baltimore, Maryland 21201 (301-528-2565).

E. GEORGE ELIAS MD
University of Maryland, Surgical Oncology Program

Baltimore City Medical Society

The Baltimore City Medical Society began its clinical year on Thursday, 5 September. At the monthly meeting President Gary L. Rosenberg MD presented a 50-year certificate to Charlotte McCarthy MD to symbolize her many years as a loyal, voting Internist.

Henry Wagner MD, past president, spoke of his ongoing dopamine studies. He needs "normals" to determine chemoreceptor distribution. Volunteers may call him at 955-3350 for details.

Albert Antlitz MD, also past president, reported the AMA activities at its recent convention. He particularly congratulated Dr. Wagner on his election to the Scientific Affairs Committee. Dr. Antlitz emphasized that the AMA is broad based and truly democratic. Through the AMA the physician practitioner can be recognized at the federal level. He justified the AMA dues increase as vital to the support of its public relations efforts, solution of the "liability" insurance crisis, and its bare-bones budget. Donald Mintzer MD and Edward Suarez-Murias MD concurred with the general sentiment that physicians must participate or be harassed.

Jack Zimmerman MD, chairman of the Professional Education Committee, introduced the evening's speaker, Judge Joseph H. Young of the United States District Court, and member of the Board of the American Cancer Society.

Judge Young showed a wide acquaintance with health care matters and a concern about "where costs are going." He declared doctors are too involved in doctoring to resolve the economics of medicine and the scientific advances prolonging our life-span. Resources *are* limited. Human suffering and cost of prolonging life versus a right-to-death decision create a moral dilemma for survivors. Should scarce resources be spent on the privileged few through the spectacular achievements of supertechnology with transplants, artifical organs, bypass procedures, and the like? Is there conversely a duty to die? When is the price of surviving too high? Health care costs us 10 percent of the GNP. Who is to decide who gets what? Should *treatment* be all important? How much should be allocated to *prevention* or to medical advances through *research*? Should the federal government control such allocation? Where then would economic entrenchment stand versus heroic treatments, in the federal perspective?

Should the limits on medical (health) care be based on age (over 65) or on defense against the contingency fee? How is our system comparable to the English system that rations health care?

Judge Young said that answers to these questions are unobtainable now. He concluded that doctors need to realize that "*there's a lot more to practice than practice.*"

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One Minute with Diabetes

I have been overweight for years, and my weight is gradually increasing. Last year I went to my gynecologist because of a vaginal infection. He did a urine and blood test and told me that I have diabetes. He recommended that I lose weight to control the diabetes and possibly prevent a recurrence of the vaginal infection. My problem is that I never eat breakfast, eat very little during the day, and cannot lose weight. I am 50 years old and have high blood pressure. What can I do so that I do not have to take insulin?

The triad of obesity, hypertension, and diabetes is common in the middle-aged population. Elliott Joslin MD is supposed to have said, "Diabetes is the penalty obese people pay for not taking care of themselves." Failure to manage the problem occurs in about 95 percent of our patients for the following reasons:

1. Lack of adequate dietary instruction
2. Lack of motivation
3. Lack of family support
4. Lack of exercise
5. Depression
6. Hidden ethanolism

When a physician makes a diagnosis of diabetes in an obese individual, he/she has the obligation to either carry out adequate dietary instruction and follow-up or to refer the person to a suitable place where it will be done.

Dietary instruction should consist of four to five hours of intensive education with monthly follow-up visits of an hour each until the weight is normal. Just giving a pharmaceutical representative's sample "diet sheet" to the patient is totally inadequate.

The treatment of obesity should be multidisciplinary: daily exercise for an hour, group therapy, behavior modification, and possibly individual psychiatric conferences for depressed and alcoholic patients. No one pattern of therapy is effective for everyone. If the physician and the patient work together closely, a weight loss program can be much more effective than it has been in the past. Just walking for one hour a day will burn off 300 calories. In 12 days one pound will be lost (3,600 calories). Set a reasonable goal of 10 to 15 pounds in three months.

Weight control is a real challenge, and many physicians do not put forth the amount of effort necessary to help the patient succeed in a weight loss program.

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Your Medical Faculty at Work

Council met on Saturday, September 28, 1985 as part of the Semi-annual Meeting and made several important decisions. The Council adopted the following resolution:

Resolved, that the Ad Hoc Committee on Professional Liability recommends to the Council that the recommendations of the AMA in connection with professional liability tort reform be endorsed; and

Resolved, that it is the belief of the Ad Hoc Committee that even these proposed reforms, if enacted, will not address the problem but will only "buy time."

Council took further action in connection with the professional liability insurance crisis and established the following protocol for a working relationship with Marylanders for Malpractice Liability Reform (MMLR):

1. Marylanders for Malpractice Liability Reform (MMLR) agrees not to hire a legislative agent.
2. If any changes in legislative objectives are made, they will be cleared through both groups.
3. MMLR agrees to abide by its objectives as spelled out in the George Wills memo and the MMLR Backgrounder.
4. Coordination of activities involving Tort Reform will continue at a high level. Representatives of both MMLR and Med-Chi will meet on a regular basis to update each group on its activities and objectives.
5. The Executive Committee of Med-Chi is directed to meet with leaders of MMLR to develop a relationship with MMLR to make it (MMLR) part of Med-Chi. The type of relationship to be explored should be similar to that between MMPAC and Med-Chi.

Council also adopted the following resolution with respect to MMLR:

The Council of the Faculty endorses the objectives of MMLR and its activities, subject to implementation of Item #5 on the above protocol.

A special session of the Council will be called for final approval of Med-Chi's relationship with MMLR as soon as the details have been worked out.

Other Council actions relating to the professional liability insurance crisis were the adoption of a resolution allowing Med-Chi to solicit a voluntary contribution of $100 from each member to support needed publicity in the upcoming months for tort reform efforts, and a resolution urging that a public relations campaign be started. Council was informed such a campaign is under way.

Council approved the following two statements developed by the Committee on Professional Ethics: Policy for Issuance of Legal and Ethical Opinions and Guidelines concerning Termination of Medical Care. Council also approved a tactical change in the Workmen's Compensation case to permit the Faculty to work with Maryland Society of Orthopedic Rehabilitation and Occupational Medicine Specialists (MSORO) in requesting a hearing before the Fee Committee on the Commission instead of an *en banc* hearing.

In other actions, Raymond M. Atkins MD was designated Assistant Secretary until the assumption of the elected post of secretary; three physicians were approved for emeritus membership; the development of a certificate of approval for outstanding committee chairmen by the Public Relations Committee was authorized; amendments to the bylaws to the Center for Health Education were approved; and three nominations were submitted to the Motor Vehicle Administration for appointment to the Medical Advisory Board.

JOHN SARGEANT CAE
Executive Director

Statement of Ownership, Management, Circulation

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Sum total 7,297; average: 7,358.

PHYSICIAN PLACEMENT SERVICE

The Medical and Chirurgical Faculty of the State of Maryland maintains a Placement Service for the convenience of Maryland physicians, hospitals and communities in search of candidates for positions available in our state. A detailed description of such opportunities should be forwarded to the Physician Placement Service, 1211 Cathedral St., Baltimore, MD 21201; telephone 1-301-539-0872.

Physicians wishing to locate in Maryland are invited to submit a resumé to be kept on file with the Physician Placement Service. Candidates are requested to inform the Faculty when they are no longer available for consideration for opportunities which might be available in Maryland.

Journal announcements on the Classified Advertising page for Physician Placement Service are charged at the regular Classified Advertising rate.

For latest information on Med-Chi Annual and Semiannual Meetings, read the **Journal** every month.

The Library Page

Medical and Chirurgical Faculty of the State of Maryland Library, 1211 Cathedral Street, Baltimore, MD 21201. Joseph E. Jensen, Librarian

1986 Periodicals

In 1986 the Medical and Chirurgical Faculty Library will add four new subscriptions to its holdings: *Clinical and Experimental Neurology*, *Journal of Clinical Immunology*, *Journal of Clinical Neuro-Ophthalmology*, and *Neurologic Clinics*. These titles were chosen on the basis of requests received from members and from periodicals most frequently cited in MEDLINE bibliographies. With the inclusion of these titles, the time interval will be decreased between request of an item and its receipt.

Selection of new periodicals is not an easy assignment. It requires many staff hours of careful monitoring of journals used by Med-Chi members. In the process of reviewing, we also can determine which periodicals were used infrequently or not at all. At the end of the year, we rank individual journal titles according to the number of different member physicians who requested each one.

Time spent in analyzing titles has proved cost effective. As the journal subscription list grows, the number of requests sent to other libraries has decreased. Time has been saved. Interlibrary loan charges from other libraries (which average around $7) and library staff time for processing have been eliminated. Physicians will not have to wait several days while we try to obtain a journal elsewhere. If we request more than six photocopies a year from a particular journal through another library, it is cheaper to subscribe.

Part of the library's goal is to direct endowed funds for subscriptions to those titles that will best serve the members of the Medical and Chirurgical Faculty. The title analysis that is performed annually brings us closer to that objective.

New Subscriptions for 1986

Clinical and Experiment Neurology
Journal of Clinical Immunology
Journal of Clinical Neuro-Ophthalmology
Neurologic Clinics

PATRICIA MUNOZ
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Selected Medical Literature Searches

The following are among the computerized medical literature searches provided to Med-Chi members during September 1985.

		No. of Citations
1.	Carbamazepine, blood, and hematologic diseases	21
2.	Cardiac rehabilitation	42
3.	Diagnosis of acquired immunodeficiency syndrome	17
4.	Evaluation studies of iontophoresis	25
5.	Gallium and lung diseases	30
6.	Physician-patient relations and confidentiality	27
7.	Physiopathology, treatment, and complications of decubitus ulcers	60
8.	Pregnancy and asthma	32
9.	Tubal sterilization and tubal pregnancy	25
10.	Ulnar nerve neoplasms	21

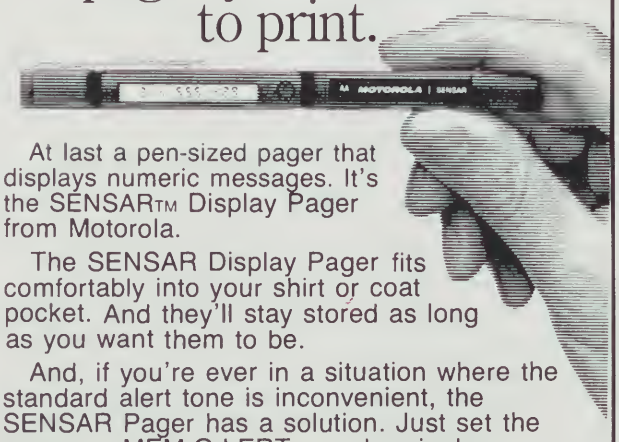
If you would like a copy of one of these searches or a search run on any biomedical topic, call or write the library.

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Federal Legislation

The *Journal of Commerce* reported that Rep. Ron Wyden (D-Oregon) plans to introduce federal legislation to address medical malpractice issues. Under the proposed bill, awards made to injured parties would be structured with one initial payment and a series of periodic payments based on the economic value of damages sustained. In addition, the bill would require the Department of Health and Human Services to keep a list of physicians found guilty of malpractice. Hospitals would be required to verify that their staff physicians were not on the HHS list, or the hospitals could be found ineligible to participate in Medicare programs.

• • •

No-Fault Malpractice Insurance

The Virginia Insurance Reciprocal will test a no-fault medical malpractice program on a limited basis. Aimed at incidents having the potential to lead to large awards, the program would allow providers to offer to pay an injured patient's economic losses without admitting fault. If the patient accepts payment, he waives his right to bring a malpractice suit; a patient who refuses payment can sue, but he must prove injury and negligence.

For more information or answers to your insurance questions, contact your insurance representative.

Record Settlement

In one of the largest pre-verdict settlements in Florida history, $7.9 million in cash was awarded to the family of a 35-year-old woman who lapsed into a coma in March 1983 after neo-synephrine, rather than xylocaine, was injected into the woman's tonsils during tonsillectomy. The patient received the wrong injection when unmarked vials of the two drugs were mistakenly interchanged in the operating room.

• • •

Consumer Surveys

In a telephone survey of 1,700 health-care consumers in New York, Penn & Schoen Associates found that 77 percent want doctors to be able to recover up to $10,000 in legal costs in cases of frivolous malpractice suits, 71 percent favor spreading the payment of large awards over a period of time instead of one lump sum, and 55 percent support a $250,000 ceiling on punitive damage awards. In addition, 57 percent of those polled thought the legal system is not well equipped to decide questions of physician liability.

In a poll of 1,500 randomly selected adults sponsored by the American Medical Association, 44 percent thought plaintiffs in malpractice suits were looking for an easy way to make money, 41 percent said that juries in malpractice cases usually award too much money, and 61 percent favored a limit on the amount of money that could be awarded to someone suing a physician for malpractice.

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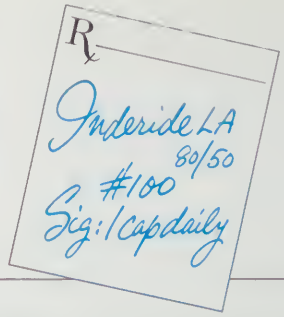
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CONTRAINDICATIONS

Propranolol hydrochloride (INDERAL®):
Propranolol is contraindicated in: 1) cardiogenic shock, 2) sinus bradycardia and greater than first degree block, 3) bronchial asthma, 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia treatable with propranolol.

Hydrochlorothiazide:
Hydrochlorothiazide is contraindicated in patients with anuria or hypersensitivity to this or other sulfonamide-derived drugs.

WARNINGS

Propranolol hydrochloride (INDERAL®):
CARDIAC FAILURE. Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated and are receiving digitalis and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle.

IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or propranolol should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction, following abrupt discontinuance of propranolol therapy. Therefore, when discontinuance of propranolol is planned, the dosage should be gradually reduced and the patient carefully monitored. In addition, when propranolol is prescribed for angina pectoris, the patients should be cautioned against interruption or cessation of therapy without the physician's advice. If propranolol therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute propranolol therapy and take other measures appropriate for the management of unstable angina pectoris. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

THYROTOXICOSIS. Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm. Propranolol does not distort thyroid function tests.

IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propranolol.

MAJOR SURGERY. The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversial. It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

Nonallergic Bronchospasm (eg, chronic bronchitis, emphysema)—PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD, IN GENERAL, NOT RECEIVE BETA BLOCKERS. INDERAL should be administered with caution since it may block bronchodilation produced by endogenous and exogenous catecholamine stimulation of beta receptors.

DIABETES AND HYPOGLYCEMIA. Beta-adrenergic blockade may prevent the appearance of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labile insulin-dependent diabetes. In these patients, it may be more difficult to adjust the dosage of insulin. Hypoglycemic attacks may be accompanied by a precipitous elevation of blood pressure.

Hydrochlorothiazide:
Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. In patients with impaired renal function, cumulative effects of the drug may develop.

Thiazides should also be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma.

Thiazides may add to or potentiate the action of other antihypertensive drugs. Potentiation occurs with ganglionic or peripheral adrenergic-blocking drugs.

Sensitivity reactions may occur in patients with a history of allergy or bronchial asthma.

The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

PRECAUTIONS

Propranolol hydrochloride (INDERAL®):
GENERAL. Propranolol should be used with caution in patients with impaired hepatic or renal function. Propranolol is not indicated for the treatment of hypertensive emergencies.

Beta-adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should be told that propranolol may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

CLINICAL LABORATORY TESTS. Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS. Patients receiving catecholamine-depleting drugs, such as reserpine, should be closely observed if propranolol is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity, which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY. Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies, in both rats and mice employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

PREGNANCY. Pregnancy Category C. Propranolol has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximal recommended human dose. There are no adequate and well-controlled studies in pregnant women. Propranolol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS. Propranolol is excreted in human milk. Caution should be exercised when propranolol is administered to a nursing mother.

PEDIATRIC USE. Safety and effectiveness in children have not been established.

Hydrochlorothiazide:
GENERAL. Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals.

All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance, namely: Hyponatremia, hypochloremic alkalosis, and hypokalemia. Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Medication such as digitalis may also influence serum electrolytes. Warning signs irrespective of cause are: Dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.

Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present or during concomitant use of corticosteroids or ACTH.

Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalemia can sensitize or exaggerate the response of the heart to the toxic effect of digitalis (eg, increased ventricular irritability). Hypokalemia may be avoided or treated by use of potassium supplements, such as foods with a high potassium content.

Any chloride deficit is generally mild and usually does not require specific treatment except under extraordinary circumstances (as in liver or renal disease). Dilutional hyponatremia may occur in edematous patients in hot weather; appropriate therapy is water restriction, rather than administration of salt, except in rare instances when the hyponatremia is life-threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy.

Insulin requirements in diabetic patients may be increased, decreased, or unchanged. Diabetes mellitus which has been latent may become manifest during thiazide administration.

If progressive renal impairment becomes evident, consider withholding or discontinuing diuretic therapy.

Thiazides may decrease serum PBI levels without signs of thyroid disturbance.

Calcium excretion is decreased by thiazides. Pathologic changes in the parathyroid gland with hypercalcemia and hypophosphatemia have been observed in a few patients on prolonged thiazide therapy. The common complications of hyperparathyroidism, such as renal lithiasis, bone resorption, and peptic ulceration have not been seen. Thiazides should be discontinued before carrying out tests for parathyroid function.

DRUG INTERACTIONS. Thiazide drugs may increase the responsiveness to tubocurarine.

The antihypertensive effects of thiazides may be enhanced in the postsympathectomy patient. Thiazides may decrease arterial responsiveness to norepinephrine. This diminution is not sufficient to preclude effectiveness of the pressor agent for therapeutic use.

PREGNANCY. Pregnancy Category C. Thiazides cross the placental barrier and appear in cord blood. The use of thiazides in pregnancy requires that the anticipated benefit be weighed against possible hazards to the fetus. These hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult.

NURSING MOTHERS. Thiazides appear in human milk. If use of the drug is deemed essential, the patient should stop nursing.

PEDIATRIC USE. Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Propranolol hydrochloride (INDERAL®):
Most adverse effects have been mild and transient and have rarely required the withdrawal of therapy.

Cardiovascular: Bradycardia, congestive heart failure, intensification of AV block, hypotension, paresthesia of hands, thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud type.

Central Nervous System: Lightheadedness, mental depression manifested by insomnia, lassitude, weakness, fatigue, reversible mental depression progressing to catatonia; visual disturbances, hallucinations, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics.

Gastrointestinal: Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, constipation, mesenteric arterial thrombosis, ischemic colitis.

Allergic: Pharyngitis and agranulocytosis; erythematous rash, fever combined with aching and sore throat; laryngospasm and respiratory distress.

Respiratory: Bronchospasm.

Hematologic: Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura.

Auto-Immune: In extremely rare instances, systemic lupus erythematosus has been reported.

Miscellaneous: Alopecia, LE-like reactions, psoriasiform rashes, dry eyes, male impotence, and Peyronie's disease have been reported rarely. Oculomucocutaneous reactions involving the skin, serous membranes, and conjunctivae reported for a beta blocker (practolol) have not been associated with propranolol.

Hydrochlorothiazide:
Gastrointestinal: Anorexia, gastric irritation, nausea, vomiting, cramping, diarrhea, constipation, jaundice (intrahepatic cholestatic jaundice), pancreatitis, sialadenitis.

Central Nervous System: Dizziness, vertigo, paresthesias, headache, xanthopsia.

Hematologic: Leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia.

Cardiovascular: Orthostatic hypotension (may be aggravated by alcohol, barbiturates, or narcotics).

Hypersensitivity: Purpura, photosensitivity; rash; urticaria, necrotizing angiitis (vasculitis, cutaneous vasculitis); fever; respiratory distress, including pneumonitis; anaphylactic reactions.

Other: Hyperglycemia, glycosuria, hyperuricemia, muscle spasm; weakness, restlessness, transient blurred vision.

Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy withdrawn.

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Editorial

Reporting Revisited

The Annotated Code of Maryland, Article 18, Sections 201 and 202, requires that all physicians report in writing diagnosed or suspected cases of certain communicable diseases. The Code of Maryland Regulations (COMAR) 10.06.01 covers the diseases and conditions, reporting procedures, and general control measures. The control of communicable diseases is a traditional endeavor in the realm of preventive medicine and public health bringing together the health care professional, consumer, and public at large for a variety of reasons.[1]

Notifying a health department of a reportable condition can be an irksome challenge to a physician. This is particularly true when placed in the context of the multitude of forms the average practitioner has to complete daily to comply with the institutional rules and regulations, federal and state statutes, and ordinances of local government. A vague feeling exists that the information will enhance studies in academic ivory towers or support a bureaucracy but never will have a practical use for the physician in the community. Further, one might assume that availability of vaccines and chemotherapeutic interventions has eliminated the major scourges of the past. This does not mean that members of the medical profession deliberately break the law or are insensitive to efforts to ensure proper surveillance, treatment, and prevention of reportable conditions.

Early in medical school curriculums major stress is placed on the inviolate nature of the physician/patient relationship and the confidentiality of information exchanged often when a patient is most vulnerable. No one would risk jeopardizing this relationship or the information exchanged. However, certain situations must be reported to the proper authorities or the physician can be considered derelict in his/her duty.[2] There are medicolegal implications for the individual, the hospital, or the health care organization when reports are not submitted promptly, particularly if a negative outcome for the public interest results from noncompliance with appropriate legal mandates.[3]

Notification of conditions to appropriate authorities is a two-way street. Nothing causes strain in the relationship between the community practitioner and the representatives of official agencies as easily as apparent nonuse of the information submitted.[2] Timely reports on the incidence, prevalence, and trends of reportable conditions are not ignored but are anticipated by individual practitioners, the press, institutions, voluntary agencies, the legislature, and consumers. In addition, rules, regulations, and ordinances should be reviewed on an ongoing basis to ensure their relevance to state-of-the-art medical care.[4] To expect voluntary reporting of conditions is not practical. This was demonstrated early on in New York when the germ theory of disease became a reality.[5]

"Viral Hepatitis Surveillance System in the State of Maryland" (which follows) is a timely update on a topic of major concern and interest to all physicians (and other members of the health care delivery team). It is a classic example of the two-way street phenomenon: getting information *back* to the practitioner. The *Journal* and the Medical and Chirurgical Faculty of the State of Maryland have played a major role in this two-way street by including the Maryland Office of Disease Control and Epidemiology's "Newsletter" since July 1984. There is ongoing concern that since the *Journal* does not reach all physicians in Maryland, this information may not have optimum impact on the health care delivery system.

We hope consideration will be given to newer and more exciting initiatives in reporting. The traditional report card could be replaced with a simple telephone call; however, at present only when a card is submitted is a physician covered medicolegally. Another step might be a "bank" of information that a practitioner can call to obtain the latest epidemiological and statistical information plus the appropriate steps to take in treatment and isolation of the patient and in evaluation of contacts.

Finally, the question of underreporting must be faced once more. Gross *et al.* reported that "only 11 percent of persons with hepatitis hospitalized in a major urban area [were] reported." Can this be substantiated as an ongoing phenomenon, or is it an isolated instance?

Certain communicable diseases were major causes of death at the turn of the century; this is in sharp contrast to the latest morbidity and mortality information available in 1985. However, reportable conditions are still an ongoing challenge. Much work has to be done by the basic scientist in the laboratory. The clinician and epidemiologist will be involved constantly now that the slide rule has been replaced by hardware and software of exponentially increasing complexity and magnitude. The medical profession always will appreciate and continue to anticipate

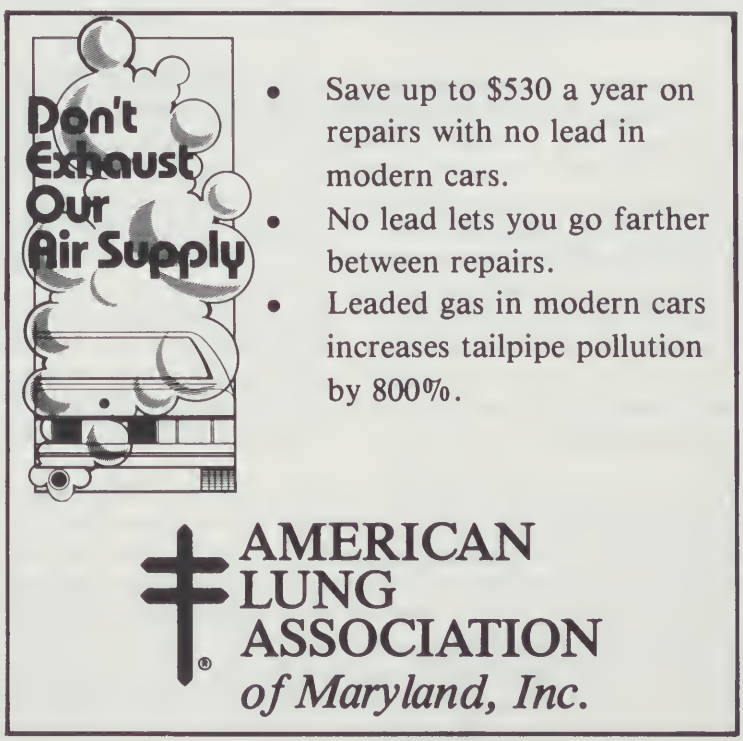
appropriate updates on material submitted to comply with reporting mandates. More importantly, this will continue to produce positive exchanges among official agencies, institutions, and the practitioner in the community.

The merits of giving individuals with specialized skills the major task of monitoring one reportable entity should be evaluated. Obviously, this generates appropriate information so that those directing programs can act correctly. However, other programs should not be neglected when skilled resources are generating information on one reportable entity. The next questions are: What should be done with this data, and what immediate impact does it have on disease control throughout the community?

JAMES P.G. FLYNN MD, MPH

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The Viral Hepatitis Surveillance System in the State of Maryland

THOMAS P. GROSS MD, CHRISTINA P. LAZAR MD, and EBENEZER ISRAEL MD

Viral hepatitis is a major public health problem in the United States. Approximately 58,000 cases were reported to the Centers for Disease Control (CDC) in 1981. The true occurrence of disease is estimated to be at least 100,000 cases of icteric hepatitis A and 50,000 cases of icteric hepatitis B annually (D. Francis *et al.*, CDC, unpublished data). Another study showed only 11 percent of hepatitis hospitalizations in a major urban area were reported.[1]

The goals of the Maryland surveillance system are to access data, control and prevent disease, monitor long-term disease trends, detect epidemics and stimulate investigations, evaluate public health disease control and prevention programs, and establish an archive for disease activity.[2] Discussion of the elements, mechanics, and quality of the system using hepatitis as a model conveys a better understanding of how communicable disease surveillance systems operate.

The authors are at the Office of Disease Control and Epidemiology, State of Maryland Department of Health and Mental Hygiene, Baltimore. Dr. Gross is at the Department on assignment from the Division of Field Services, Epidemiology Program Office, Centers for Disease Control, Atlanta, Georgia.

The viral hepatitis surveillance system in Maryland began in 1919. Cases were listed under the category of jaundice; however, it was three years before a case of jaundice was reported. Three cases were reported in 1922 and two the following year. Beginning in 1936, cases were listed under the category of infectious hepatitis. In 1976, viral hepatitis surveillance in Maryland became part of a national hepatitis surveillance program conducted through CDC. Three types of viral hepatitis are included in the Maryland hepatitis surveillance system: A, B, and non-A-non-B (NANB).

The methods of the surveillance system have changed since 1919. Made in response to the advent of blood tests for hepatitis A and B, these changes use laboratory results to determine hepatitis type (Table 1). With the institution of the complement fixation test for hepatitis B surface antigen (HBsAg), cases listed as "infectious hepatitis" prior to 1969 now were listed as "infectious" (HBsAg−, hepatitis A) or "serum hepatitis" (HBsAg+, hepatitis B). A "hepatitis unspecified" category was added in 1975 when it became clear that some cases of hepatitis were HBsAg− but did not fit a definition of hepatitis A based on their incubation periods and epidemiologic characteristics. After further milestones in hepatitis serology, a category for NANB hepatitis was created in 1981. A diagnosis of NANB now relies on results of hepatitis A and B blood tests (Table 2, next page).

Public Health Importance

Reported incidence of viral hepatitis in Maryland by type from 1978 to 1982 is illustrated in Figure 1, next page. From a total population of 4.22 million in 1982, the reported incidence of hepatitis B was 17.7 cases per 100,000 population (over 700 cases), well above the national level of 9.6. For hepatitis A it was 4.1 cases per 100,000 population (over 200 cases), well below the national level of 10.1. The reported incidence for hepatitis unspecified was 2.9 cases per 100,000 population (over 100 cases), below the national level of 3.8. The reported incidence of NANB hepatitis in Maryland in 1982 was 2.3 cases per 100,000 population (over 100 cases) (no national data available for comparison).

In addition to incidence data, another estimate of the public health importance of hepatitis is cost. Cost of care for acute hepatitis B only is presented. This estimate is based on assumptions used by Schatz in his analysis of the economic effects of hepatitis B in the United States: only 10 percent of all cases of hepatitis B are reported; only half those with hepatitis B are symptomatic; 16 percent of those symptomatic are hospitalized; 1 percent of persons hospitalized develop ful-

Table 1. Maryland State Laboratory Tests: Date Instituted and Corresponding Surveillance Change

Laboratory Test*	Date Instituted	Surveillance Change
CF HBsAg	1967	
	1969	Hepatitis A vs. Hepatitis B
CIE HBsAg	1971	
RIA HBsAg	1974	
RIA anti-HBs	1975	Hepatitis Unspecified
RIA anti-HAV-IgM	1978	
RIA anti-HBc	1978	
RIA HBeAg	1979	
RIA anti-HBe	1979	
	1981	Non-A, Non-B Hepatitis

* CF = Complement fixation
CIE = Counterimmune electrophoresis
RIA = Radioimmunoassay
HBsAg = Hepatitis B surface antigen
Anti-HBs = Hepatitis B surface antibody
Anti-HBc = Hepatitis B core antibody
HBeAg = Hepatitis B e antigen
Anti-HBe = Hepatitis B e antibody
Anti-HAV-IgM = Hepatitis A antibody (immunoglobulin M)

Table 2. Viral Hepatitis Case Definitions, Maryland, 1984

Hepatitis A
1. Anti-HAV-IgM positive or
2. Physician's diagnosis of hepatitis A, HBsAg negative, and supportive epidemiologic data (for example, age, life-style)

Hepatitis B
1. HBsAg positive and recent onset of illness (may need to rule out chronic recurrent disease) or
2. Anti-HBc positive and recent onset of illness (may need to rule out chronic recurrent disease) or
3. HBsAg positive and increased liver enzymes or
4. HBsAg positive, anti-HBc positive, and anti-HBs positive

Non-A, Non-B
1. Anti-HAV-IgM negative, and either HBsAg negative or anti-HBc negative and
2. Recent onset of illness

Unspecified
1. Physician's diagnosis of hepatitis (but not as to type) and
2. HBsAg negative or no available lab tests

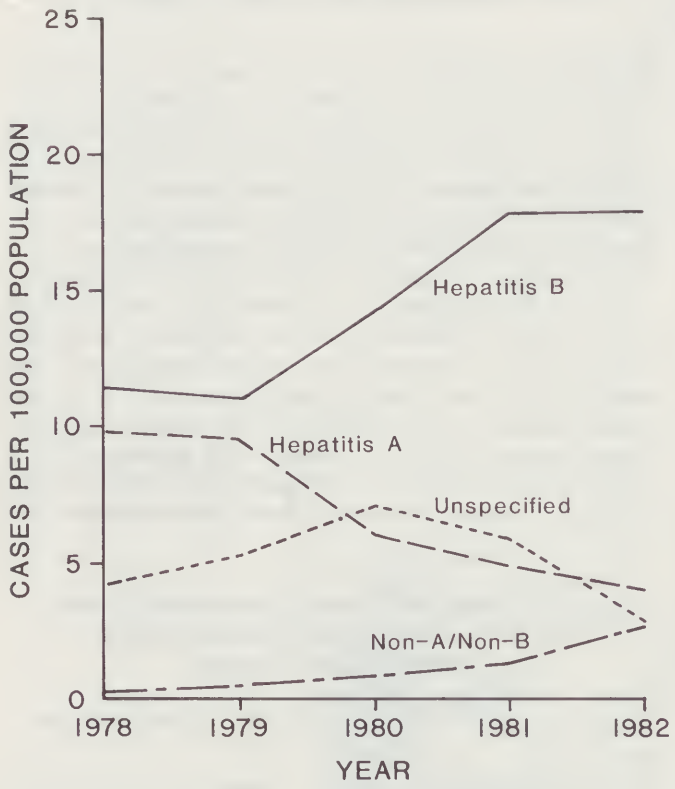


Figure. Viral hepatitis rates, by type and year, Maryland, 1978–1982.

minant hepatitis; asymptomatic persons incur no acute costs; and costs for medical services are based on charges in the Phoenix area during early 1981 (G. Schatz *et al.*, CDC, unpublished data). There were 762 reported cases of hepatitis B in Maryland in 1982; thus, we can extrapolate there were 7,620 total cases, 3,810 symptomatic cases, 610 hospitalized hepatitis patients, and 3,200 symptomatic nonhospitalized hepatitis patients. Estimated costs for those hospitalized are $4,855 per case (total: $2,961,550); for those symptomatic, but not hospitalized $1,316 per case (total: $4,211,200); and for those who develop fulminant disease (6 cases) $8,549 per case (total: $51,294). The estimated total cost is $7,224,000.

Surveillance System

Elements Primary data sources used in the hepatitis surveillance system are the Maryland Confidential Morbidity Report (CMR); the Interstate Reciprocal Notification of Disease Report; private, county, and State Health Department laboratory reports; certificates of death from the Maryland Center for Health Statistics; CDC viral hepatitis case record (surveillance form); and telephone reports by physicians to county or State Health Departments.

Mechanics The CMR is the backbone of the surveillance system. The Code of Maryland Regulations on Communicable Diseases requires this report be filed with the county health department on each acute case of any type of viral hepatitis.[3] Although physicians are not solely responsible for submitting reports, they constitute the bulk of reporting sources.[3]

A CMR's first integration with other data sources occurs at the physician level. Most physicians obtain the necessary demographic, clinical, and laboratory data before sending a CMR to the county health department. Although it is discouraged by counties, telephone reports rather than sending a CMR are done by some physicians. If a hepatitis-related death occurs, some physicians may note the required information on a CMR, or a death certificate alone may be forwarded.

Data integration next occurs at the county level. Active solicitation for further information (demographic, clinical, or laboratory) to complete a CMR submitted by a physician varies by county health department. Some counties may wait for confirming laboratory data, submitted by physician or laboratory (private, county, or state), before forwarding a CMR to the State Health Department. Other counties may send reports (for example, a complete or incomplete CMR or laboratory report) to the state as they are received. If laboratory test results are received by the county health department but an accompanying CMR is not

on record, the physician may be requested to submit a CMR and/or a surveillance form. Some counties request physicians to submit surveillance forms as a routine part of reporting.

At the state level, incoming reports (for example, CMRs, laboratory reports, and surveillance forms) submitted primarily by county health departments and laboratories, are cross-referenced to reports on file by the state surveillance epidemiologist. In addition, death certificates coded for viral hepatitis by the Maryland Center for Health Statistics are sent to the state surveillance epidemiologist for evaluation. Again, physicians or county health departments may be asked by the state surveillance epidemiologist to obtain further supportive, demographic, clinical, or laboratory data.

Vigorous attempts are made to obtain complete CMRs and surveillance forms before computer coding of the data. Approximately 90 to 95 percent of CMRs received during one week are coded that week.

Information gathered at the state level is transferred to CDC, Division of Viral Diseases, Hepatitis Branch. Completed surveillance forms are sent to CDC two to three times a month. The total number of reported cases of hepatitis by type are sent to CDC on a weekly basis. CDC publishes weekly totals of reported hepatitis by type in *Morbidity and Mortality Weekly Report*. They also publish a computerized fact sheet that lists information on the various types of hepatitis by total numbers per state, by physician versus serologic diagnosis, and by epidemiologic characteristics; however, the fact sheet is published two years after the information has been gathered.

Quality The quality of a surveillance system for a specific disease can be judged, in part, by its case definition, timeliness, and sensitivity. In Maryland, case definitions for different types of viral hepatitis rely greatly on the results of blood tests (Table 2). Use of laboratory data by the surveillance epidemiologist in the disposition of cases is especially important with hepatitis since one type of hepatitis can be clinically indistinguishable from another.

Blood tests may have to be supplemented with other data to define a case. For example, any infant or toddler with symptoms of hepatitis is more likely to have hepatitis A; therefore, epidemiologic data such as age may be helpful. To define a case as acute hepatitis B, the surveillance epidemiologist may need to rule out recurrent disease through information supplied by the physician. In addition to the criteria in Table 2, a certain degree of judgment must be used in defining cases. Finally, for the data to reflect disease incidence in Maryland residents, foreign travelers or residents of other states who develop hepatitis while in Maryland are not counted as Maryland cases.

The timeliness of the system was calculated after reviewing approximately 400 CMRs from the first half of 1983. The type of hepatitis reported was not examined. The mean number of days from date of onset of disease to date of report from the county health department was 16.1 days with a range of 2 to 92 days. A better estimate of the timeliness of the system would rely on date of diagnosis and not date of onset; however, the former usually is not available. The mean number of days from date of report from the county health department to the date received at the State Health Department was 11.7 days with a range of 2 to 66 days. The date of report from the county may be either the date the CMR was received or the date it was mailed to the State Health Department.

The surveillance system does not generate negative reports; thus, the sensitivity (proportion of persons with the condition that are identified by the surveillance system) of the system cannot be calculated but can be discussed only in general terms. Most of the sensitivity of the system is lost because many infected persons are asymptomatic. These people account for the majority of hepatitis cases. Further losses in sensitivity occur when symptomatic individuals may not see a physician due to mild symptoms or financial reasons. A physician may not recognize the symptoms as those of hepatitis; if recognized, the type of hepatitis may be inaccurately classified if appropriate laboratory tests are not ordered. A loss in sensitivity also may occur through laboratory error.

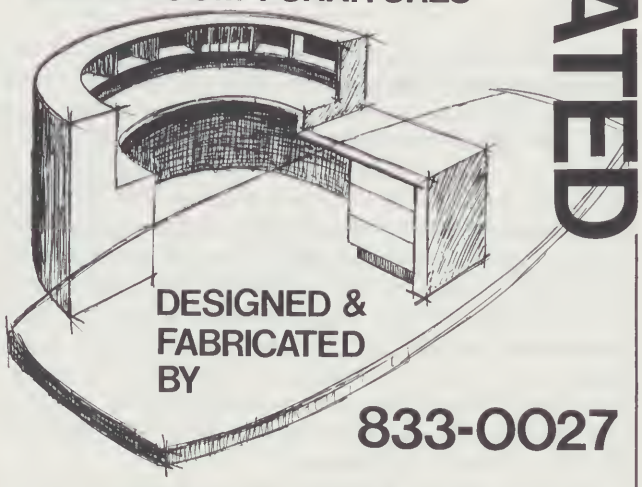
However, the second greatest loss in sensitivity occurs due to physician underreporting of disease. Marier[1] noted that only 11 percent of persons with hepatitis hospitalized in Washington, DC in 1971 were reported by physicians. Lastly, some county health departments, as well as physicians, do not pursue possible contacts of cases. These departments, as well as the State Health Department, receive HBsAg+ reports from sources such as blood-donor and drug-abuse centers. Most of these reports are filed as carriers and are not investigated.

Comments

This information is representative of communicable disease surveillance. As with any surveillance system, the hepatitis surveillance system has strengths and weaknesses.[4] The strengths include vigorous attempts (most notably at the state level) to obtain accurate and complete morbidity reports supplemented with appropriate blood test results; use of multiple data sources in collating information; adherence to strict case definitions that do not rely solely on physician diagnosis; and efforts in contact tracing as part of prevention strategy

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(for example, giving immune globulin to persons with hepatitis A). The weaknesses include lack of time for data analysis at the state and county levels, widespread underreporting of disease (mostly at the physician level[1]) and lack of timeliness in obtaining morbidity reports. These strengths and weaknesses underscore the fact that the usefulness of any surveillance system largely depends on the quality of its input: accuracy, completeness, relevance, and timeliness.

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Cost Analysis of AIDS Cases in Maryland

RANDY BERGER MD

During the first half of 1985, 69 newly diagnosed cases of AIDS were reported to the Maryland Department of Health and Mental Hygiene (DHMH). Planning for the epidemic has been difficult. This report is the first cost analysis of AIDS cases in Maryland. The projected hospital cost for AIDS patients in 1985 is $4,125,000. More than likely this is a conservative estimate.

The study was done at the DHMH Office of Disease Control and Epidemiology while Dr. Berger was a resident in the Department of Epidemiology and Preventive Medicine, University of Maryland. Dr. Berger is now at DHMH, 201 West Preston Street, Baltimore, Maryland 21201.

Acquired immune deficiency syndrome (AIDS) has become the public health epidemic of the 1980s. Nationally, the number of AIDS cases is increasing exponentially with a doubling of total reported cases every 6 months.[1] Maryland's current experience indicates a doubling of cases every year. For the Baltimore/Metropolitan area, it is predicted there will be in excess of 150 new cases diagnosed in 1985. Only 50 of the AIDS patients diagnosed in 1985 are expected to be living by year's end.

There have been several reports estimating the costs generated by AIDS patients. The University of California estimated that a patient with AIDS will require two to three months of hospitalization at a cost of $50,000 to 100,000 per patient.[1] Two other studies estimate hospital costs for an AIDS patient at $42,000 (based on a lifespan of 224 days following first hospitalization) and $140,000 respectively.[2,3] In the latter study, the Center for Disease Control (CDC) estimated that AIDS patients are hospitalized an average of 169 days at a cost of $830 per day.[3] In fiscal year 1985 federal spending on AIDS was $92.78 million; $13.7 million (14.8 percent) went toward treatment costs.[4]

The importance of these cost estimates becomes obvious. This study proposed to estimate the hospital cost in Maryland of caring for an AIDS patient and to determine who is paying the bill. With an estimate of such costs, alternative care (such as hospice care) can be evaluated on a cost-containment basis.

Methods

Hospital medical record numbers were gathered from files at Baltimore City Department of Health and Maryland State Department of Health and Mental Hygiene (DHMH) for reported AIDS cases in the Baltimore/Metropolitan area. Only men with no known hospitalizations out of state were eligible for inclusion. A list of medical record numbers corresponding to AIDS-related hospital admissions was submitted to the Information Service Center (ISC) for summary discharge information. The ISC is an independent nonprofit organization providing health care data.

Results

Between 1979 and February 2, 1985 there were 122 cases of AIDS reported to DHMH. Sixty were from the Baltimore/Metropolitan area. For 53.3 percent (32/60) of these cases it was possible to find hospital medical record numbers. Seven cases were excluded prior to analysis, 4 cases had hospitalizations occurring during the first quarter of 1985 and cost information was unavailable, and 3 cases had hospitalizations out of state. Therefore this report is based on information from 43.3 percent (26/60) of reported AIDS cases in the Baltimore/Metropolitan area.

Demographic characteristics of the group are representative of all cases reported to DHMH (Table 1). The 26 cases had 66 hospital admissions at 18 hospitals under 29 Diagnostic Related Groups (DRGs), accounting for 1,286 days of hospitalization at a cost of $697,536. Over a third (38.5 percent) had hospitalizations prior to the time DHMH had a reported diagnosis

Table 1. Characteristics of Maryland and Study Sample AIDS Cases

	Maryland State		Study	
	Number	Percent	Number	Percent
Total Cases	122		26	
Characteristics				
Sex				
Male	112	92	22	84.6
Female	10	8	4	15.4
Race				
Black	66	54	13	50
White	53	44	13	50
Hispanic	3	2		
Risk Factor				
Gay or bisexual male	76	63	14	53.8
IV drug user	18	15	5	19.2
Haitian immigrants	3	2	0	0
Hemophiliac/blood product recipient	3	2	1	3.8
Unknown	22	18	6	23.1
Age				
Under 20	1	1	0	0
20–29	26	21	6	23.1
30–39	51	42	9	34.6
40–49	34	28	8	30.8
Over 50	10	8	3	11.5
			mean 37.4 (s.d. ± 10) range 20–59	

of AIDS for the patient. Prior hospitalizations that had data available were used in analysis. The average lifespan during which hospitalizations occurred was 168 days; this was calculated by averaging time intervals from diagnosis to death for all cases. The vast majority (23/26) died during hospitalization. All 26 patients died during the study period. Length of hospital stay (LOS) ranged from 1 day to 146 days, the median LOS was 32 days, the average length of stay (ALOS) was 19.5 days.

The average cost per patient day was $542. Depending on DRG the cost per day ranged from $1,628 under DRG 001 craniotomy to $165 under DRG 460 burns. Nine DRGs characterize 78.8 percent of the admissions (Table 2). Average length of stay and average cost per DRG for AIDS cases was compared to Maryland state statistics. Only eight DRGs were used for this comparison. DRG 468 is considered to be a "wastebasket" with unreliable data.

AIDS patients do not fit well into a DRG model. For 75 percent (6/8) of the eight most common AIDS-related DRGs, the ALOS of AIDS patients was greater than the Maryland ALOS and the Medicaid day limit. Cost was also greater than the state average for 75 percent (6/8) of DRGs. The most likely admitting diagnosis for an AIDS patient was DRG 398, reticuloendothelial and immunity disorders. For DRG 398 the average cost for an AIDS patient and state cost were approximately $480 per day, but AIDS ALOS was greater than the state ALOS. When cost is weighed by probability of a DRG admission, expected DRG cost and DRG ALOS, the weighed cost per day of hospitalization for an AIDS patient is $550.

Medicaid was the source of payment for 19.7 percent (13/66) of the admissions, accounting for payment of 14 percent of hospital cost. Approximately 19 percent (5/26) of the study population had Medicaid coverage. Two Medicaid recipients were intravenous drug abusers, risk category was unknown for two recipients, and one was gay. Three Medicaid patients also had admissions where source of payment was listed as self-pay.

Discussion

If in 1985 there are 150 newly diagnosed cases of AIDS with an estimated 2.5 hospital admissions per case and an ALOS of 20 days per admission, the total cost of these patients would be $4,125,000. The estimated cost per patient in Maryland is $27,500. This is considerably less than the $42,000 to 140,000 range previously reported.[1,2,3] Using the conservative cost figure found in this study, the 1985 Maryland cost for AIDS of $4,125,000 is still staggering. This figure does not take into account out-of-hospital cost, which can be substantial: months of home hyperalimentation, home nursing care, and the indirect cost of lost wages.

Table 2. Comparison by DRG of AIDS ALOS and Cost to Maryland State and Medicaid

DRG Description	DRG Number	Number of AIDS Admissions	AIDS ALOS*	MD ALOS	Medicaid Day Limit	AIDS Cost/Day	MD Cost/Day
Major chest procedure	075	6	39	17	29	$702	$579
Respiratory infections & inflammations Age > = 70 and/or CC†	079	4	14	15	21	736	452
Esophagitis, gastrent, & mis. digest. dis age > = 70 and/or CC	182	3	20	7	8	432	347
Minor skin disorders age = > 70 and/or CC	283	3	17	7	7	628	347
Other OR procedures of the blood & blood forming organs	394	4	20	7	11	447	621
Reticuloendothelial & immunity dis. age = > 70 and/or CC	398	12	16	9	8	489	482
Reticuloendothelial & immunity dis. age = < 70 w/o CC	399	6	8	5	6	487	409
OR procedure for infections & parasitic dis.	415	5	16	19	27	733	480
Unrelated OR proc	468	9	31			438	

* average length of stay
† complications

Table 3. Cost Comparison by Care Facility Average Estimates†

Option	Services Provided										$Cost/ Day
	Room	Board	Personal Services	Health Aids	Social Services	Nursing Care	Physician	Medication	Laboratory	Ancillary Therapy	
Shelters (State)											
Emergency	+	+	±								20
VNA*				+	+	+					45
											65
Project Home	+	+	+								27
VNA*				+	+	+					45
											72
Adult Foster Care	+	+	+								18
VNA*				+	+	+					45
											63
Volunteer Home Placement	+	+	+								0
VNA*				+	+	+					45
											45
Nursing Home (Medicaid)	+	+	+	+	+	+					49
Domiciliary (State)	+	+	0								17
VNA*				+	+	+					45
											62
Free Standing Hospice (Private)	+	+	+	+	+	+			+	+	175
Rehabilitation Center (State)	+	+	+	+	+	+	+	+	+	+	304
Acute Care Hosp	+	+	+	+	+	+	+	+	+	+	550

* VNA–Visiting Nurse Association estimate (cost for hospital-based home health service is estimated to be $62/day)
† Prepared by Norman Dean MD while a resident at Johns Hopkins University.

In contrast to the 14 percent of hospital costs Medicaid paid for AIDS cases, Medicaid paid 9 percent of all hospital costs in fiscal year 1984. It is likely that the three Medicaid patients who also had admissions listed as self-pay had no financial coverage for these admissions. Depending on when Medicaid coverage for AIDS patients is initiated, the cost may be greater than 20 percent.

While all acute care hospital costs cannot be eliminated for this fatal disease, ALOS in acute care hospitals can be reduced. In San Francisco alternative settings in the community are available and the ALOS for AIDS hospitalization is eight to ten days. In Los Angeles County alternative settings have not been supported and the ALOS is 21 days (personal communication), similar to the ALOS found in Maryland.

At DHMH a work group was assembled to address the medical and housing needs of AIDS patients. Part of the goal of appropriate case management is to minimize use of acute care hospitalization. Planning for the placement of AIDS cases is made difficult by lack of data on the numbers of cases in need of service by level of care. The natural course of illness is characterized by periods of remission and periods of severe debilitation. A wide range of care alternatives have been considered: home care, adult foster care, nursing homes, hospice care, volunteer home care, rehabilitative centers, hospitals with existing excess beds, and group homes (Table 3). It is obvious that any alternative setting would be less expensive than the cost of an acute hospitalization. Cost-effective management of AIDS will encourage the development of alternative care settings.

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Comprehensive Rehabilitation of Head Injured Adults

JOHN D. RANSEEN PhD

Traumatic head injury increasingly is being recognized as a serious national health problem. An estimated 7 million head injuries in the United States each year result in 100,000 deaths, 500,000 hospitalizations, and more than 50,000 individuals left with significant deficits that impair full independent living.[1,2] Advances in emergency medical care have allowed many accident victims to survive an injury that previously would have resulted in death. Treatment of these individuals is a complex challenge for health care professionals as well as for society at large, particularly when it comes to providing rehabilitative services.[3] Only recently in Maryland have efforts been stimulated to provide comprehensive rehabilitation designed specifically for head injured patients.

Ranseen is Clinical Neuropsychologist at Montebello Hospital, Head Injury Rehabilitation Program, University of Maryland Medical System (MIEMSS), Rehabilitation Program.

The process of rehabilitation is illustrated in this case of a 19-year-old, single male, who was involved in a motorcycle accident and sustained a closed head injury and multiple leg fractures that resulted in an above-the-knee amputation. He displayed a fluctuating level of consciousness at the scene of the accident but subsequently became comatose. Responsive only to deep pain on admission to MIEMSS, his Glasgow Coma Scale was 9, indicative of a moderate closed head injury. A CAT scan on admission was interpreted as normal. Nevertheless, he showed transition in cognitive and behavioral functioning consistent with a severe closed head injury involving prolonged confusion and posttraumatic amnesia (PTA). Within one week he was described as functioning consistent with a level 4 on the Rancho Scale, being intermittently agitated, completely disoriented, confused, and exhibiting a disturbed sleep cycle. His agitation was managed with psychotrophic medication. Occupational and physical therapies were initiated during acute care to help manage the patient and to structure his day. Within two weeks (although he remained disoriented) with strong direction and structure he could perform basic self-care and began ambulating with a walker under close supervision.

He was deemed medically stable and transferred to Montebello Hospital for rehabilitation approximately one month postinjury. At Montebello he remained disoriented with severe short- and long-term memory impairments, poor judgment, and no self-awareness. Consequently, the patient remained in a period of posttraumatic amnesia highly indicative of a severe closed head injury that likely would require long-term rehabilitation and planning.

The patient was unable to comprehend the loss of his leg and consequently was a safety concern requiring 24-hour supervision. Therapeutic and nursing staffs geared their interactions with the patient toward fostering his awareness of his circumstances. With firm directions and structure, the patient would participate for short periods of time in therapies to initiate basic self-care and preambulation skills. Within six weeks the patient's agitation decreased, and he showed a basic awareness of his circumstances (Rancho 6) despite poor short-term memory and retention of learning.

Before his injury the patient was a stable young man planning to move from the reserves to active marine duty. He had one year of college and was living at home. The family was informed that, while the course of recovery strongly suggested a return to basic independent living was anticipated, serious deficits preventing employment were likely. Supervision and care by the family would be necessary. Eight weeks postinjury the patient was deemed safe for home visits to help him and his family understand and compensate for both physical and cognitive deficits in a familiar environment.

Approximately 11 weeks postinjury the patient appeared to be stabilizing cognitively. He was able to meet the basic demands of the hospital, showed retention of learning from day to day, self-initiated therapeutic activities, and displayed appropriate interpersonal behavior. Cursory evaluation showed no readily apparent residual cognitive deficits. Nevertheless, a neuropsychological evaluation performed three months postinjury revealed significant diffuse cognitive impairment in terms of intellectual decline, reduced memory and learning capacity, slow and concrete thought processes, and reduced auditory comprehension. Although the patient could meet the basic demands of independent living with minimal supervision, he was clearly not fit for employment or continued education at that time.

The patient was discharged from inpatient rehabilitation approximately four months postinjury with follow-up services provided by the Center for Living, which offers day treatment and psychosocial support to patients and their families. This program provided a comprehensive six-month treatment plan of resocialization, adjustment to disability, counseling, and cognitive remediation. Subsequently the patient was capable of completing a vocational evaluation at Maryland Vo-

cational Rehabilitation Center. Approximately two years postinjury he completed this evaluation and was recommended for training in bookkeeping and basic accounting.

Although many aspects of this case were not discussed, it illustrates that rehabilitation of a patient with a closed head injury with a normal CAT scan can extend over a two-year period. This patient now is able to ambulate with a prosthesis, and, although he retains cognitive deficits, he has learned to compensate for these problems so they do not greatly impair his life. Over this two-year period the patient has learned to accept the changes in his life resulting from his injuries but only after prolonged effort and help by a number of people at a variety of facilities.

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The National Head Injury Foundation and its Maryland chapter (which have provided the primary impetus for these efforts) view head injury as a silent epidemic since the individual's disabilities often are not readily apparent.[2] Physical deficits resulting from a head injury are generally much less debilitating than dysfunctions in cognition, behavior, and emotional control that impair the individual educationally, vocationally, and socially.[4-7] The tragedy is compounded since it characteristically strikes young adults, usually male, and radically alters their ability to function successfully within adult roles. Only with comprehensive rehabilitative efforts will some of these victims be able to reach a successful adaptation to their environment.

Nevertheless, an understanding of the most efficacious treatment strategies for head injured patients has not been achieved.[6] In fact, at this time there is no consensus as to a unified theory of head injury rehabilitation.[8] Consequently, head injury rehabilitation is often a confusing concept to many physicians who traditionally have been trained to view brain damage resulting from neurological insult as an irreversible condition.

Management During Acute Care

The first priority for the traumatically head injured patient is rapid, efficient medical care to manage and limit the myriad complications arising from the injury. Edema, hemorrhaging, and raised intracranial pressure are often more devastating than the damage from actual impact and contrecoup of a head injury.[9] Upon admission and during the early hospital course certain information concerning severity of the injury is important to document, not only for diagnostic reasons but also to provide a systematic way to communicate the patient's level of functioning with other health care professionals. This is particularly important in making some tentative early predictions concerning prognosis and, consequently, the patient's need for future intensive rehabilitation services.

The Glasgow Coma Scale has standardized the reporting of coma level on admission and is being used widely; it is simple, reliable, and can be gathered systematically by medical support personnel.[10] Based on the patient's best visual, verbal, and motor responses, it provides a rating of the depth of the coma. It also can serve as a measure of the rate of change in the patient's functioning when it is reported at set intervals. This scale has been shown to correlate, albeit weakly, with the general functional outcome of the patient.[5] Other indicators found to provide prognostic significance include initial CAT scan findings[11], actual duration of coma[12], and duration of posttraumatic amnesia (PTA).[13] Neurological indices including presence of a hematoma and absence of oculovestibular responses correlate with poor outcome.[14]

Some evidence suggests that PTA is the best predictor of residual cognitive impairment.[15] PTA generally is defined as the period of severe confusion head trauma patients usually display during which new memories cannot be stored.[16] Unfortunately this tends to be a very subjective evaluation, which compromises its reliability. To attain greater objectivity in the measure of PTA, scales have been developed to assess basic orientation and recall. Probably the most widely used is the Galveston Orientation and Amnesia Test (GOAT) employed in serial assessment of a patient to determine the degree and duration of cognitive confusion.[17]

Different physicians label the general severity of a head injury, based on neurodiagnostic procedures including the Glasgow Coma Scale on admission, in a variety of ways. As a general rule, a Glasgow Coma Scale of 8 or below on admission indicates a severe closed head injury.[18] Using this as a criterion, however, will mislabel individuals with higher scores whose functioning deteriorates over time. A duration of PTA greater than seven days generally is viewed as reflecting a severe, generalized head injury.[16] These various measures, in conjunction with findings on the CAT scan and other neurodiagnostic procedures, are extremely useful in characterizing the early recovery phases of the head injured patient. Taken together they can provide an estimate of the severity of the injury and consequently some indications concerning the patient's probable outcome in terms of cognitive functioning and ability to live independently.

Continual evaluation and monitoring of the patient's cognitive and behavioral status can be facilitated by a scale developed at Rancho Los Amigos Hospital.[19] The

Rancho Scale describes eight stages in the natural recovery process of a closed head injured patient from a level 1 comatose patient to a level 8 patient who functions independently. This scale is designed to provide basic treatment strategies for maladaptive behaviors exhibited at the various stages.[20]

Generally the middle stages (4 and 5), characterized cognitively by severe confusion, disorientation, and memory impairment coupled with behavior marked by periods of agitation, present the most significant management problems within the hospital. Some evidence suggests that managing agitation with psychotrophic medication (often standard practice) tends to increase the duration of cognitive confusion.[21] Consequently, with select patients, simple environmental alterations to reduce the overall level of stimulation may have a sufficiently calming effect and may allow management of the agitated patient on a reduced level of medication.

Use of support personnel during acute care to begin a formal rehabilitation process is strongly encouraged. Nursing (as well as physical, occupational, and speech therapies) can be employed to provide ongoing evaluation of the patient's cognitive status and to give appropriate levels of stimulation. This helps the patient reorganize basic thought processes by relearning simple skills. Support personnel should design a basic structure of care that provides the consistency necessary for the head injured patient.

The trauma rehabilitation program at MIEMSS has begun to meet the specific needs of head injured patients by forming a group of support personnel to function as a rehabilitation treatment team. Sequential Glasgow Coma Scale scores obtained by the nursing staff provide a picture of the patient's early course of recovery. From admission, physical, occupational, and speech therapists not only serve as consultants but also provide ongoing daily treatment to initiate the rehabilitation process. Each therapy uses the Rancho Scale to assess progress and to design programs appropriate to the patient's cognitive and behavioral status. This information is coordinated through family services to help the family understand the nature of the injury and the patient's behavior and make decisions concerning the need for formal rehabilitation services. Additionally, the various therapists at MIEMSS and Montebello meet regularly to discuss likely candidates for inpatient rehabilitation thus coordinating care at all levels.

Communication with Family

Outcome is a difficult concept to quantify. For a physician, an acceptable outcome may be a patient who, despite a very severe injury, is alive yet remains in a persistent vegetative state. Most would argue that outcome must consider the quality of life of the individual including ability to live independently and return to usual activities. Consequently, many factors contribute to overall outcome including premorbid stability, family support, and financial resources.

While all the measures previously mentioned correlate with outcome to some extent, there is great individual variation in recovery patterns due to the interaction of these factors. Some patients with very severe head injuries make an excellent recovery, return to work, and may be left with only mild residual memory impairment. Others with seemingly mild head injuries experience poor outcome in terms of ongoing cognitive and social impairment. Except in extreme cases, the earlier a prediction of outcome is made, the less likely it will be accurate.

Obtaining measurements (such as the Glasgow Coma Scale and duration of PTA) provides a standard for communicating with health care professionals involved in patient rehabilitation. It is vitally important as a basis for communicating to the patient's family an initial understanding of the injury and its possible impact on both the patient's and the family's lives. This is one of the most important and sensitive aspects of early rehabilitation efforts.[22]

Although no firm guidelines for communicating a patient's prognosis to the family can be offered (given the tenuous nature of early prediction), some knowledge of outcome based on the indicators previously discussed facilitates this process. It is necessary to admit the uncertainty of early prediction while trying to encourage realistic, yet cautious, optimism. Unfortunately, our experience suggests that physicians often are uncomfortable providing ambiguous information to families concerning prognosis. While some tend to make unnecessarily gloomy predictions that the patient will remain vegetative and dependent, others offer the family an unrealistic picture of near total recovery. Additionally, it is common for families to receive highly contradictory information from the various physicians attending the case. The process of family acceptance of such an injury and its impact must be initiated during acute care by providing as accurate information as possible, particularly regarding the need to pursue ongoing rehabilitation resources.

Inpatient Rehabilitation

Once medical complications have been controlled, the need for formal rehabilitation services must be addressed. In the case of relatively minor head injuries, there is usually no need for inpatient rehabilitation. However, recent evidence suggests that a significant percentage of patients who have suffered a relatively

minor closed head injury (Glasgow Coma Scale = 13 to 15) will exhibit subjective complaints of headache, irritability, and memory impairment, sometimes for many months.[23] Further, evidence of subtle cognitive impairment on neuropsychological measures, in the absence of observable structural impairment on neurodiagnostic procedures, often can be demonstrated in these patients. Reports suggest that approximately 25 percent of the minor head injury patients report ongoing complaints that may disrupt their ability to return to school or work.[23] Often these problems have been exacerbated by the fact that they are not taken seriously and such patients have been labeled malingering. If complaints continue over a number of weeks, a formal neuropsychological evaluation is indicated to fully assess residual impairment in cognitive functioning and to make recommendations for treatment approaches.

Patients with extensive physical and cognitive deficits require inpatient rehabilitation. Rehabilitation centers generally have varying criteria for inclusion in their head injury programs and may include patients at widely differing levels of functioning. For example, criteria for inclusion in the program at Montebello include medical stability of the patient, evidence the patient has shown some improvement in cognitive and behavioral functioning during the acute care course, and evidence the patient displays some basic ability to follow simple, one-step commands. Other centers are equipped to care for lower-level patients in comas or persistent vegetative states.

Currently, the fundamental concept in head injury rehabilitation treatment is that a variety of health care specialists work together to guide the patient's natural recovery process and to promote patient movement toward greater functional independence. Although medical issues require constant monitoring, inpatient rehabilitation for the head injured is not primarily a medical process but rather an educational and psychosocial one. Rehabilitation specialists focus on helping patients learn lost skills and new ways to compensate for deficits they are unlikely to recover. Most head injury rehabilitation teams include a physiatrist specializing in the medical management of rehabilitation patients; a physical therapist remediating physical impairments; an occupational therapist helping the patient learn basic self-care and community skills; a speech therapist evaluating swallowing mechanisms and providing therapy for language and communication impairment; nursing staff implementing continuous medical and therapeutic programs; a neuropsychologist assessing cognitive functioning and facilitating the management of behavioral problems; and the social worker providing support and ongoing communication with families, helping families manage economic issues, and assisting in the referral process for aftercare services. Although each member has a specific function, the key for effective rehabilitation is that all work in a coordinated manner toward specific, common goals tailored to the individual patient's needs.

A main goal of head injury rehabilitation is the cognitive remediation of a patient who has lost basic thinking skills ranging from simple orientation to the environment and short-term memory to complex skills of thinking critically, making effective decisions and judgments, and showing self-awareness of interpersonal behavior. "Cognitive remediation" and "cognitive retraining" have become virtually synonymous with treatment of head injuries. Unfortunately, these terms can be confusing and may be viewed differently by various experts in the field.[8] In general, cognitive remediation refers to a variety of techniques employed to improve the patient's orientation to his/her environment,[24] memory and learning,[25] perceptual motor skills,[26] basic decision making and judgment capacities,[27] language abilities,[28] and interpersonal effectiveness.[27]

A common misunderstanding is that cognitive remediation is the activity of a single discipline. Effective head trauma rehabilitation necessitates that cognitive remediation be viewed as an overall attitude and approach coordinated between all members of the rehabilitation team. Thus, all therapies must constantly promote the patient's reorientation to the environment, and all team members must structure their interactions in a manner that promotes effective communication, teaches appropriate interpersonal behavior, facilitates recall and decision making, and so on. Without coordination and overlap among the disciplines, rehabilitation becomes a fragmented and ineffective process. Additionally, not only must therapists consistently interact in a manner that promotes increased cognitive functioning, but also the overall program and the environment created within the rehabilitation hospital must be designed in a manner that recognizes the patient's cognitive limitations while attempting to facilitate remediation.

At Montebello Hospital head injured patients live in a relatively self-contained unit with separate therapeutic clinics allowing greater control over the environment. These patients have great difficulty adapting to change in their environment. Therefore, a basic structure and consistency in therapeutic routine is established to minimize change and to decrease confusion. Since memory impairment is evident in virtually all head injured patients, the unit is structured with numerous visual and physical cues (such as schedule boards, photographs of the rehabilitation team members, and records of daily events) to facilitate recall. Having a self-contained rehabilitation unit allows many

therapeutic activities to be done in a group format that promotes cooperating and sharing among the patients and facilitates the process of the patient beginning to identify him or herself as head injured.

While the main goal during inpatient stay is to increase the functional independence of the patient through increasing cognitive functioning and behavioral competence, another critical goal is to help the family and patient understand and accept changes resulting from this type of injury. This is a difficult process with head injured patients for a variety of reasons. Changes associated with head injury are diverse and complex, making them difficult to communicate to the family and the patient. During the acute care and rehabilitation phases the patient may change dramatically from day to day or even from hour to hour. The family has a hard time absorbing these changes and understanding what they mean. Additionally, brain damage often has numerous adverse connotations (including mental retardation and psychosis) that need to be addressed with the family.

Frequently the patient has difficulty comprehending the injury and consequently the need for hospitalization. This often is a result of the patient's inability to cognitively process the meaning of the injury due to the nature of the damage. Head injured patients have extremely limited ability to self-reflect and consequently are unaware their behavior and thought processes have changed. Families characteristically exhibit a great deal of denial, harboring a fantasy that the patient eventually will be restored to normal.

At Montebello, regular family conferences and individual counseling sessions provide ongoing feedback to the family on the patient's status to help them understand the changes resulting from the head injury. Families are encouraged to take the patient home on weekends during the inpatient phase for progressively longer trial visits to view the patient's functioning closely in a familiar environment. The family has the opportunity to experience how changes in the patient will affect family life. Even with adequate preparation, both patients and families often do not realize the impact of a head injury until after patient discharge from the rehabilitation hospital. Management of psychological and emotional trauma is of great importance at this point.

Aftercare Services for Head Trauma Patients

The goal of rehabilitation is not to restore the patient to normal functioning but rather to guide and stimulate the natural recovery process to a point where the family and the community are prepared to accept the patient. Despite the most effective acute care and rehabilitation services, a large percentage of head injured patients will retain cognitive, behavioral, and physical deficits that require continued rehabilitation services on an outpatient basis.

Unfortunately, programs specifically designed to meet the demands of head injured patients in Maryland (as in most states) do not exist or do not have adequate funding to handle a large volume of patients. Step-down programs including ongoing day treatments, transitional living facilities, and group homes oriented toward head injured adults are badly needed. Although various mental retardation and psychiatric after care programs may share common goals, they usually are inappropriate for head injured patients who have needs different from psychiatric patients and who are unable to identify with these populations. The Montebello Head Injury Program, with its strong liaison to MIEMSS, has formed a working relationship with the Center for Living, which offers day treatment and psychosocial support to patients and their families. More such programs are needed. Vocational rehabilitation in Maryland is beginning to see a greater need for specific programs geared toward the complex needs of the head injured patient who often is inappropriate for traditional, competitively oriented training programs.

Secondary problems that must be actively addressed with many head injured patients are alcohol and substance abuse. Consistent with other centers, figures at Montebello during the first year of operation revealed that approximately half the head injured patients had a premorbid history of alcohol and/or substance abuse.[29] The majority of these individuals had been involved in alcohol-related accidents.

As a general rule individuals tend to return to previous behaviors and coping strategies during periods of stress. The period of adjustment posthospitalization is often the most stressful. Consequently, many head injured patients return to previous maladaptive habits that can retard recovery and leave them more prone to future injuries. One of the highest risk groups for head injury are those individuals with previous head injuries. Since there are no programs specifically designed to deal with this problem in a head injured population, existing alcohol treatment programs must be used.

Montebello Program

The MIEMSS and Montebello coordination is an attempt to provide comprehensive rehabilitation to head injured patients. A smooth transition for inpatients and their families is facilitated by ongoing communication between the departments at MIEMSS and Montebello. Additionally, therapists regularly rotate between the two settings to better coordinate treatment

strategies within disciplines. Initial efforts have been rewarding. Demographic information concerning 69 patients who participated in rehabilitation at Montebello Hospital during the initial 12 months of specialized head trauma rehabilitation is shown in Table 1. Consistent with all previous epidemiological studies, the majority of head injured patients were young males.[30] Table 2 indicates the modal type of injury was a closed head injury due to a motor vehicle accident. Acute care records indicate that the mean Glasgow Coma Scale on admission to MIEMSS was approximately 8 (Table 2) indicative of a severe injury.

Table 3 provides some general outcome data on these patients. The majority (96 percent) were discharged to home to live with family or relatives. The majority of these patients were reported by their families to require minimal or no supervision and care to live independently. Approximately one third, however, were noted to require active management and supervision by the family. A subjective rating by the author also indicates (Table 3) that approximately one third of the patients retain moderate to severe cognitive and physical deficits preventing a return to full, independent living.

A more revealing indication of outcome is return to work. Table 3 indicates that approximately 55 percent of this population, who were employed prior to their injury, had returned to work in a full- or part-time capacity, usually within about three to six months after discharge from the hospital. Forty-one percent had not been able to return to work, generally because continued physical and cognitive impairment prevented them from meeting previous job demands. Additionally, a large percentage (37 percent) of this population was unemployed prior to the injury, a reflection of the generally low socioeconomic status of many of these patients.

It must be emphasized these figures do not necessarily reflect the positive benefits of rehabilitation since they do not constitute a controlled study. Nevertheless, they are indicative of the fact that many individuals with severe closed head injuries who receive rehabilitation services can make an adequate adjustment.

Follow-up surveys with these patients and their families indicate that the majority report at least subtle cognitive impairments in terms of poor recall, mild difficulties with language, poor attention and concentration, and decreased mental stamina. Many families indicate the patient "seems different," apparently in reference to the subtle personality changes that often are a sequelae to closed head injury. These findings are comparable to previous outcomes studies.[6,7,12]

Table 1. Demographic Characteristics of Head Injured Patients: Consecutive Admissions Over 12 Months to Montebello Hospital (N = 69)

	Percent
Sex	
Male	83
Female	17
Age	
15–25	45
25–35	28
35–45	10
Over 45	17
Race	
White	66
Nonwhite	24

* Education (Mean years) = 10

Table 2. Type, Cause, and Severity of Head Injury: Consecutive Admissions Over 12 Months to Montebello Hospital (N = 69)

	Percent
Type	
Closed	91
Penetrating	6
Other	3
Cause	
MVA	48
Fall	18
Pedestrian	12
Assault	9
GSW	6
Severity	
Glasgow Coma Scale on admission to acute care (mean): 8	
# Days hospitalized acute care (mean): 36	

Table 3. General Outcome Following Inpatient Rehabilitation: Montebello Hospital Head Injured Patients (N = 69)

	Percent
Living arrangements	
To home	96
Institutionalized	2
Group home	2
Degree of disability (subjective rating)	
Severe	7
Moderate	24
Mild to normal	69
Return to Work* (N = 44)	
Unable	41
Part-time	15
Full-time	44

* Unemployed prior to injury = 37

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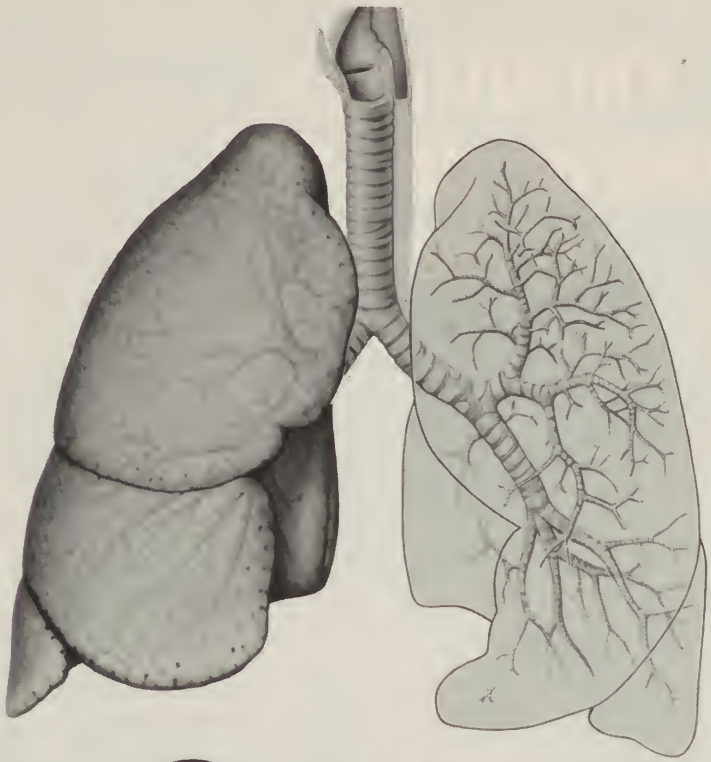
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Indications and Usage: Ceclor* (cefaclor, Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms

Lower respiratory infections, including pneumonia caused by *Streptococcus pneumoniae (Diplococcus pneumoniae), Haemophilus influenzae*, and *S. pyogenes* (group A beta-hemolytic streptococci).

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Ceclor.

Contraindication: Ceclor is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

Warnings: IN PENICILLIN-SENSITIVE PATIENTS, CEPHALOSPORIN ANTIBIOTICS SHOULD BE ADMINISTERED CAUTIOUSLY. THERE IS CLINICAL AND LABORATORY EVIDENCE OF PARTIAL CROSS-ALLERGENICITY OF THE PENICILLINS AND THE CEPHALOSPORINS, AND THERE ARE INSTANCES IN WHICH PATIENTS HAVE HAD REACTIONS, INCLUDING ANAPHYLAXIS, TO BOTH DRUG CLASSES.

Antibiotics, including Ceclor, should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to drugs.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins); therefore, it is important to consider its diagnosis in patients who develop diarrhea in association with the use of antibiotics. Such colitis may range in severity from mild to life-threatening.

Treatment with broad-spectrum antibiotics alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by *Clostridium difficile* is one primary cause of antibiotic-associated colitis.

Mild cases of pseudomembranous colitis usually respond to drug discontinuance alone. In moderate to severe cases, management should include sigmoidoscopy, appropriate bacteriologic studies, and fluid, electrolyte, and protein supplementation. When the colitis does not improve after the drug has been discontinued, or when it is severe, oral vancomycin is the drug of choice for antibiotic-associated pseudomembranous colitis produced by *C. difficile*. Other causes of colitis should be ruled out.

Precautions: *General Precautions* — If an allergic reaction to Ceclor* (cefaclor, Lilly) occurs, the drug should be discontinued, and, if necessary, the patient should be treated with appropriate agents, e.g., pressor amines, antihistamines, or corticosteroids.

Prolonged use of Ceclor may result in the overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Positive direct Coombs' tests have been reported during treatment with the cephalosporin antibiotics. In hematologic studies or in transfusion cross-matching procedures when antiglobulin tests are performed on the minor side or in Coombs' testing of newborns whose mothers have received cephalosporin antibiotics before parturition, it should be recognized that a positive Coombs' test may be due to the drug.

Ceclor should be administered with caution in the presence of markedly impaired renal function. Under such conditions, careful clinical observation and laboratory studies should be made because safe dosage may be lower than that usually recommended.

As a result of administration of Ceclor, a false-positive reaction for glucose in the urine may occur. This has been observed with Benedict's and Fehling's solutions and also with Clinitest® tablets but not with Tes-Tape* (Glucose Enzymatic Test Strip, USP, Lilly).

Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Usage in Pregnancy — Pregnancy Category B — Reproduction studies have been performed in mice and rats at doses up to 12 times the human dose and in ferrets given three times the maximum human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Ceclor* (cefaclor, Lilly). There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers — Small amounts of Ceclor have been detected in mother's milk following administration of single 500-mg doses. Average levels were 0.18, 0.20, 0.21, and 0.16 mcg/ml at two, three, four, and five hours respectively. Trace amounts were detected at one hour. The effect on nursing infants is not known. Caution should be exercised when Ceclor is administered to a nursing woman.

Usage in Children — Safety and effectiveness of this product for use in infants less than one month of age have not been established.

Adverse Reactions: Adverse effects considered related to therapy with Ceclor are uncommon and are listed below.

Gastrointestinal symptoms occur in about 2.5 percent of patients and include diarrhea (1 in 70).

Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely.

Hypersensitivity reactions have been reported in about 1.5 percent of patients and include morbilliform eruptions (1 in 100). Pruritus, urticaria, and positive Coombs' tests each occur in less than 1 in 200 patients. Cases of serum-sickness-like reactions (erythema multiforme or the above skin manifestations accompanied by arthritis/arthralgia and, frequently, fever) have been reported. These reactions are apparently due to hypersensitivity and have usually occurred during or following a second course of therapy with Ceclor. Such reactions have been reported more frequently in children than in adults. Signs and symptoms usually occur a few days after initiation of therapy and subside within a few days after cessation of therapy. No serious sequelae have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome.

Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy.

Other effects considered related to therapy included eosinophilia (1 in 50 patients) and genital pruritus or vaginitis (less than 1 in 100 patients).

Causal Relationship Uncertain — Transitory abnormalities in clinical laboratory test results have been reported. Although they were of uncertain etiology, they are listed below to serve as alerting information for the physician.

Hepatic — Slight elevations in SGDT, SGPT, or alkaline phosphatase values (1 in 40).

Hematopoietic — Transient fluctuations in leukocyte count, predominantly lymphocytosis occurring in infants and young children (1 in 40).

Renal — Slight elevations in BUN or serum creatinine (less than 1 in 500) or abnormal urinalysis (less than 1 in 200).

[061782R]

Note: Ceclor* (cefaclor, Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillin-allergic patients.

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

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Contraindications: Severe left ventricular dysfunction (see *Warnings),* hypotension (systolic pressure < 90 mm Hg) or cardiogenic shock, sick sinus syndrome (except in patients with a functioning artificial ventricular pacemaker), 2nd- or 3rd-degree AV block. **Warnings:** ISOPTIN should be avoided in patients with severe left ventricular dysfunction (e.g., ejection fraction < 30% or moderate to severe symptoms of cardiac failure) and in patients with any degree of ventricular dysfunction if they are receiving a beta blocker. (See *Precautions.)* Patients with milder ventricular dysfunction should, if possible, be controlled with optimum doses of digitalis and/or diuretics before ISOPTIN is used. (Note interactions with digoxin under *Precautions.*) ISOPTIN may occasionally produce hypotension (usually asymptomatic, orthostatic, mild and controlled by decrease in ISOPTIN dose). Elevations of transaminases with and without concomitant elevations in alkaline phosphatase and bilirubin have been reported. Such elevations may disappear even with continued treatment; however, four cases of hepatocellular injury by verapamil have been proven by rechallenge. Periodic monitoring of liver function is prudent during verapamil therapy. Patients with atrial flutter or fibrillation and an accessory AV pathway (e.g. W-P-W or L-G-L syndromes) may develop increased antegrade conduction across the aberrant pathway bypassing the AV node, producing a very rapid ventricular response after receiving ISOPTIN (or digitalis). Treatment is usually D.C.-cardioversion, which has been used safely and effectively after ISOPTIN. Because of verapamil's effect on AV conduction and the SA node, 1° AV block and transient bradycardia may occur. High grade block, however, has been infrequently observed. Marked 1° or progressive 2° or 3° AV block requires a dosage reduction or, rarely, discontinuation and institution of appropriate therapy depending upon the clinical situation. Patients with hypertrophic cardiomyopathy (IHSS) received verapamil in doses up to 720 mg/day. It must be appreciated that this group of patients had a serious disease with a high mortality rate and that most were refractory or intolerant to propranolol. A variety of serious adverse effects were seen in this group of patients including sinus bradycardia, 2° AV block, sinus arrest, pulmonary edema and/or severe hypotension. Most adverse effects responded well to dose reduction and only rarely was verapamil discontinued. **Precautions:** ISOPTIN should be given cautiously to patients with impaired hepatic function (in severe dysfunction use about 30% of the normal dose) or impaired renal function, and patients should be monitored for abnormal prolongation of the PR interval or other signs of excessive pharmacologic effects. Studies in a small number of patients suggest that concomitant use of ISOPTIN and beta blockers may be beneficial in patients with chronic stable angina. Combined therapy can also have adverse effects on cardiac function. Therefore, until further studies are completed, ISOPTIN should be used alone, if possible. If combined therapy is used, close surveillance of vital signs and clinical status should be carried out. Combined therapy with ISOPTIN and propranolol should usually be avoided in patients with AV conduction abnormalities and/or depressed left ventricular function. Chronic ISOPTIN treatment increases serum digoxin levels by 50% to 70% during the first week of therapy, which can result in digitalis toxicity. The digoxin dose should be reduced when ISOPTIN is given, and the patients should be carefully monitored to avoid over- or under-digitalization. ISOPTIN may have an additive effect on lowering blood pressure in patients receiving oral antihypertensive agents. Disopyramide should not be given within 48 hours before or 24 hours after ISOPTIN administration. Until further data are obtained, combined ISOPTIN and quinidine therapy in patients with hypertrophic cardiomyopathy should probably be avoided, since significant hypotension may result. Clinical experience with the concomitant use of ISOPTIN and short- and long-acting nitrates suggest beneficial interaction without undesirable drug interactions. Adequate animal carcinogenicity studies have not been performed. One study in rats did not suggest a tumorigenic potential, and verapamil was not mutagenic in the Ames test. *Pregnancy Category C:* There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy, labor and delivery only if clearly needed. It is not known whether verapamil is excreted in breast milk; therefore, nursing should be discontinued during ISOPTIN use. **Adverse Reactions:** Hypotension (2.9%), peripheral edema (1.7%), AV block: 3rd degree (0.8%), bradycardia: HR < 50/min (1.1%), CHF or pulmonary edema (0.9%), dizziness (3.6%), headache (1.8%), fatigue (1.1%), constipation (6.3%), nausea (1.6%), elevations of liver enzymes have been reported. (See *Warnings.*) The following reactions, reported in less than 0.5%, occurred under circumstances where a causal relationship is not certain: ecchymosis, bruising, gynecomastia, psychotic symptoms, confusion, paresthesia, insomnia, somnolence, equilibrium disorder, blurred vision, syncope, muscle cramp, shakiness, claudication, hair loss, macules, spotty menstruation. **How Supplied:** ISOPTIN (verapamil HCl) is supplied in round, scored, film-coated tablets containing either 80 mg or 120 mg of verapamil hydrochloride and embossed with "ISOPTIN 80" or "ISOPTIN 120" on one side and with "KNOLL" on the reverse side. Revised August, 1984. 2385

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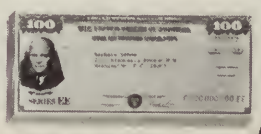


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MIEMSS: Topics of Interest

Center for Living: Trauma Aftercare and Outcomes

MARGARET M. EPPERSON-SEBOUR MSW and ELAINE W. RIFKIN MSW

An estimated 100,000 people die each year from severe head injury and an additional 600,000 are injured seriously enough to require hospitalization. Of these, 30,000 to 50,000 are left with behavioral or intellectual dysfunction that precludes return to a normal life.[1] Young people disabled from such injury currently cost society more than $1 billion each year.[2] As a result, emphasis during the last few years has shifted from acute medical management to long-term rehabilitation and reintegration services.[3–7] The Center for Living, a community based program that is the terminus of the Maryland Institute for Emergency Medical Services Systems continuum of care concept, is designed to provide the comprehensive educational, vocational, psychosocial, and family support services necessary to bridge the gap between physical restoration and productive, independent function.

Epperson-SeBour is Director of the Psychosocial Services Department of the Maryland Institute for Emergency Medical Services Systems. Rifkin is Clinical Director at the Center for Living.

The advanced technology of trauma hospitals coupled with sophisticated communication systems that permit the rapid evacuation of patients from accident scenes have created a population of seriously injured patients that did not exist ten years ago.[8,9] The majority of these are single, working men under 30 years old who recently have been emancipated from their families. Most have been involved in life-threatening motor vehicle, industrial, or recreational accidents that have resulted in head injury.

Traditionally the patient with serious injuries has been discharged from the acute care hospital to an inpatient rehabilitation center for physical restorative services. After receiving maximum benefit from these services, the patient has been discharged to home with little or no follow-up or has been moved to a vocational evaluation and training center. This progression of services, however, has not been effective in reintegrating head-injured and other polyinjured victims into their families, communities, and jobs. The current trend is toward a continuum of care (Figure 1, next page) with treatment that starts at the accident scene, continues through the acute medical and rehabilitation settings, and concludes with a community based program for reintegration services.[10–13]

The Center for Living (CFL), which is certified by the State of Maryland Division of Rehabilitation, includes components to meet the patients' primary needs on discharge from an inpatient rehabilitation setting. These components include (a) effective diagnostics tailored to measure deficits and strengths for designing appropriate plans of action, (b) psychosocial and cognitive therapies offered in a group setting, including peer support and review,[4,5] (c) family intervention, (d) networking with community resources in a team approach, and (e) patient advocacy (Figure 2, next page).

The Maryland Institute for Emergency Medical Services Systems (MIEMSS) is the state agency providing emergency patient care in the prehospital environment and in trauma and other specialty referral centers throughout Maryland. Clinicians are invited to submit manuscripts concerning emergency, trauma, and critical care medicine. Send manuscripts to Carl A. Soderstrom MD, Topics Editor, MIEMSS, 22 South Greene St., Baltimore, MD 21201.

Client Population

CFL serves multiply injured trauma clients from the MIEMSS Shock Trauma Center and other trauma centers in the Maryland Emergency Medical Services System whose physical rehabilitation needs are addressed by rehabilitation programs but who need structured psychosocial therapy in order to successfully return to the community. Clients who benefit from CFL are those with spinal cord injuries, closed head injuries causing organic brain dysfunction, multiple bone fractures causing residual limb dysfunction, burn patients who have restricted movement and/or physical disfigurement, or any combination of the above. Although MIEMSS statistics show most of these trauma victims are young males, CFL is open to any trauma client who requires its service. The family of the client often needs psychosocial services as much as the trauma recoverer. Therefore, the CFL offers a family systems approach to treatment.

The CFL eventually will offer job reorientation education and respite/residential care; however, the most immediate need of our clients is for psychosocial services.

Services

Psychosocial Evaluation Prior to acceptance in a CFL program area, the trauma recoverer and family participate in an evaluative process designed to gather information to determine the appropriateness of referral. The evaluation begins with a psychosocial interview with the trauma recoverer to assess level of functioning. Attention is paid to memory, premorbid history, appropriateness of response, attention span, attitude toward referral, and stated goals.

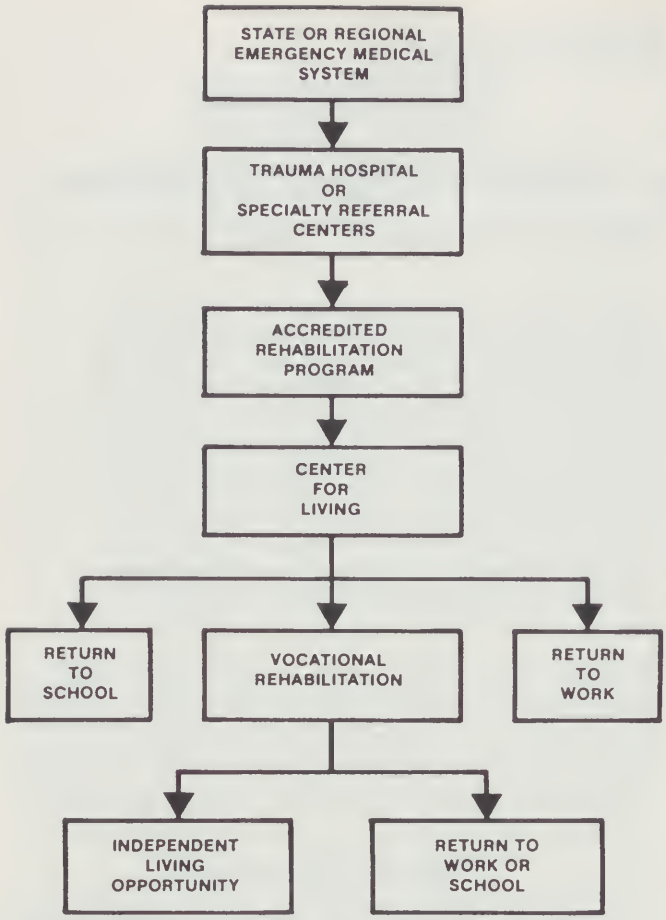


Figure 1. Continuum of care concept

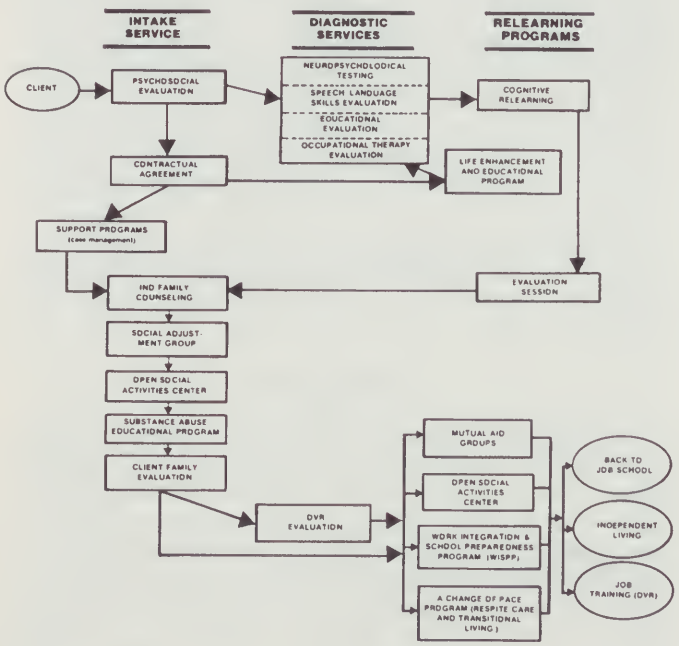


Figure 2. Client flow-through system

Following this one-to-one interview, the family is invited to share in the process, thereby adding a critically important family dimension to CFL programming. From the first contact the explicit expectation is that the family will play an important role in the psychosocial rehabilitative process. Additionally, important elements in the psychosocial functioning of the recoverer are observed by encouraging family interaction during the evaluation period. During the family interview, miscommunication is avoided by offering information relating to program goals and objectives. After the evaluation, the family has a clear understanding of the CFL program and of the responsibility expected of them if they are to become center participants. Further, the recoverer is relieved of the burden of pursuing rehabilitation without a family system support.

Clinical Counseling Program After the initial psychosocial assessment, clients have the opportunity to select individual, group, and family modalities in clinical counseling. These counseling sessions are an important element in reintegrating trauma clients into the community. Therapy is structured to reestablish and strengthen the individual and social support resources that will sustain that trauma recoverer and the family as readjustment progresses.

Case Management After evaluation, clients not yet active in a program area are case managed by the social worker evaluator. The client and the family may need help with community resources and will benefit by having an advocate at the CFL.

Life Enhancement and Education Program (LEEP) This twelve-week structured psychosocial program gives trauma recoverers an opportunity to relearn social skills and to develop internal controls so their general behaviors are again socially acceptable.

To be ready for this group situation, recoverers may need to be at least six months posttrauma and ready to deal with sensitive psychosocial issues. The LEEP team includes a dance and movement therapist as coordinator, a psychodramatist, a social worker, a speech pathologist, and an occupational therapist.

In addition to expressive therapies, recoverers participate in didactic sessions covering areas such as communication skills, assertiveness training, decision making, sexuality, and substance abuse. Guest speakers are invited to participate in the program when appropriate.

Cognitive Relearning Program (CORE) This twelve-week, structured, educational day program offers students with deficits caused by head trauma the opportunity to focus on problems in communication, daily living activities, academics, and social skills. The CORE team includes a special educator as coordinator, a speech pathologist, an occupational therapist, a social worker, and a psychologist.

Through differential diagnosis and specifically designed exercises, the student's cognitive abilities can be increased or alternate modes of functioning can be developed.

Neuropsychological Evaluation The majority of CFL clients (94 percent) (Table 1) have experienced head trauma and benefit from a diagnostic tool to distinguish organic from functional disability. Comprehensive neuropsychological testing for head trauma victims is necessary in designing a comprehensive plan for trauma recoverers.

As a result of extensive testing, followed by a sensitive interpretation session with client and family, realistic goals are set and appropriate therapies ordered.

Communication Disorders Program The Communication Disorders Program provides trauma recoverers with a speech, language, and cognitive skills evaluation to determine their level of cognitive abilities for placement in LEEP, CORE, or individual therapy. Individual therapy emphasizes improving the realm of cognitive skills and basic language functions secondary to the sequelae of head trauma. All services are provided by speech and language pathologists certified by the American Speech and Hearing Association and licensed by the state of Maryland.

Occupational Therapy Individualized Treatment Program The Occupational Therapy Program provides trauma recoverers with evaluation in the perceptual-cognitive, motor, and community living skills areas to assist in determining clients' vocational and independent living potential. The treatment component includes programs for the LEEP and CORE groups as well as an individualized therapy program. Occupational therapy for the LEEP and CORE programs concentrates on strengthening clients' cognitive, perceptual, and community living skills. In the individual treatment program, any motor deficits hindering the client's vocational capabilities are addressed. The Social Center,

Table 1. Center for Living Client Demographic Information* (March 1981–June 1985)

	Percent		Percent
Sex		Employment status	
Male	80	Employed	16
Female	20	Unemployed	84
Age		Race	
20 and under	20	Caucasian	86
21–25 years	30	Black	14
26–30 years	21	Residence	
31–35 years	11	Baltimore City	32
36 and over	18	Baltimore County	22
Education		Anne Arundel County	20
Some high school	30	Harford County	7
High school grads	37	Prince George's County	6
Some college	20	Howard County	3
College grads	7	Carroll County	2
Trade school	3	Wicomico County	2
Some elementary	3	DC	1
Disability cause		Frederick County	1
Head injury	94	Montgomery County	1
Spinal cord injury	3	Out of state	1
Gas inhalation	1	St. Mary's County	1
Orthopedic injury	1	Caroline County	0.5
Amputation	1	Dorchester County	0.5
Posttrauma		Type of accident	
6 months or less	17	Motor vehicle	71
6 months to 1 year	26	Gunshot	7
1–2 years	25	Recreational	7
More than 2 years	32	Industrial	6
Marital status		Hypoxia	3
Married/no children	5	Aneurysm	2
Married/children	20	Assault	2
Sep/div since trauma	5	Fall	2
Sep/div before trauma	14	Alcohol involved in accident	38
Unmarried	56		

* Information based on trauma recoverer at intake. Total = 285.

which provides informal leisure activities for clients, also comes under the supervision of the Occupational Therapy Services. These services are provided by a certified and licensed occupational therapist at the Master of Science level.

Social Center The Social Center offers an opportunity to redevelop social skills and test social acceptability. Group and individual activities provide opportunities for clients to practice new skills in a protective setting.

Dance/Movement Therapy Dance/movement therapy is a body movement and mental health therapy that complements the physical dysfunctions of trauma recoverers. Physiological and psychological aspects of the trauma are treated simultaneously. Neuromuscular organization seems to increase organization. With a loss of body functioning, a corresponding loss of body awareness and emotional control usually occurs. The movement process evokes thoughts and feelings and brings them to a conscious level to be addressed. As new adaptive movement patterns and expressive and communicative behaviors emerge and are learned, trauma recoverers increase their independence and effectiveness in interacting with their environment.

Substance Abuse Education Many trauma recoverers report they often experience social isolation, depression, anger, and guilt because of their mental and/or physical impairments, which may prevent them from returning to their pretrauma level of functioning. This state of mind can make the trauma client more vulnerable to substance abuse. Substance abuse education provides the client with accurate information and services related to alcohol and drugs. Guest speakers, lectures, and films help dispel myths by replacing them with facts.

Didactic Speakers Didactic sessions include guest speakers (neurosurgeons, physicians, nurses, and former shock trauma recoverers) from MIEMSS and other health agencies. Topics are chosen by clients, and speakers address issues such as the functioning of the central nervous system and the ramifications of traumatic injury, pharmacological effects of drugs, health maintenance practices, as well as the pragmatic issues of transportation and independent living opportunities.

Related Programs Important support for the Social Center are two volunteer groups that will use the Center for Living for their programs: the Trauma Recovery Group and Families United for Trauma Rehabilitation (FUTR). The Trauma Recovery Group is an incorporated volunteer self-help network of mutiply injured trauma recoverers who were patients at MIEMSS Shock Trauma Center and have returned to the community. This group meets biweekly to discuss and exchange experiences. FUTR is a family support network/consumer advocate group comprised of trauma recoverers and family members.

Future Programs Future programs will include job and education reorientation and respite care for clients. The goal of the CFL is the return of clients to the community, which necessitates job training and additional education programs.

Respite care will provide opportunity for trauma recoverers to spend time in a supervised residential setting while offering families reprieve from day-to-day care, which may further encourage families to stay together.

Program Evaluation It is incumbent on any program to continually test its effectiveness in meeting stated goals. It seems especially important that great care be taken in gathering information pertaining to the long-term psychosocial adjustment of the trauma recoverer. Regardless of one's orientation in the philosophical debate on extension of life, the responsibility remains to provide programs to improve quality of life following acute hospitalization.

Ten years ago, trauma recoverers with the level of disability now being served by the CFL did not survive their injuries. With improved medical care, more than 80 percent (Table 1) of these patients (mostly young men just beginning adulthood) survive devastating injuries. With proper intervention, many may look forward to a productive future. Conversely, without help they may face institutionalization which could, over time, produce a huge financial burden to society.

From CFL's inception, its staff has accepted the responsibility to gather demographic information, to keep statistics regarding services, and to develop evaluative mechanisms to determine program effectiveness. In addition, programs are responsive to changing needs of the trauma recoverers and their families in order to provide the best opportunity for goal attainment.

Outcomes

The total number of clients treated at the CFL from its start in March 1981 until June 1985 is 712 (Table 2). Of this number, 285 are trauma recoverers, and 427 are family members. Of the 285 trauma-recovered clients, 118 were admitted into the CFL's day treatment programs (LEEP and CORE) (Table 3). Of the 118 day program participants, 84 clients (68 in LEEP and 16 in

Table 2. Number of Clients at the Center for Living (March 1981–June 1985)

Trauma recoverers	285
Family members	427
Total	712

CORE) have completed treatment, and their cases have been closed. Thirty-four of the day program participants are currently in treatment at the CFL. The data in Tables 4 and 5 reflect the outcomes of the 84 clients whose cases have been closed.

Time and Cost

Trauma recoverers completing either LEEP and/or CORE who then entered educational or training programs spent an average of 19 months at the CFL (from psychosocial evaluation to closure). Eighty-eight percent of this group participated in the psychosocial day program (LEEP). Fifty percent went on to complete the educational day program (CORE). The average cost of services to this group while at the CFL was $4,173, or $220 per month.

Trauma recoverers who completed LEEP and/or CORE and then returned to work spent an average of 18 months at the CFL (from psychosocial evaluation to closure). Twenty-nine percent of this group participated in the psychosocial day program (LEEP). Eighty-six percent completed the educational day program (CORE). The average cost of services to this group while at the CFL was $5,208, or $289 per month.

Conclusion

Preliminary outcomes from LEEP and CORE indicate the programs are, in great part, meeting goals of reintegrating clients to their families and communities by their having developed greater productivity levels (returning to work or school), more independent functioning, and a satisfying life action plan.

The initial client sample is small, but it is a valuable indicator of the programs' effectiveness in view of the paucity of such information.[13] All clients completing the programs will be followed one to five years after discharge to determine the long-term cost-effectiveness of the CFL's efforts in offering day treatment programs.

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Table 3. Day Treatment Programs

	Number of Clients (n = 118)
LEEP	
Closed cases	68
Currently active in CFL	16
CORE	
Closed cases	16
Currently active in CFL	18

Table 4. LEEP Outcomes (May 1982–June 1985)

	Closed Cases	
	Number	Percent
Returned to work	3	4
Accepted into an education or job training program	15	23
Doing volunteer work	2	3
Deinstitutionalized and independent in activities of daily living (ADL)	1	1.5
Report improved quality of life within home and community	4	6
Graduated into CORE	21	31
Entered independent living situation	1	1.5
Total positive outcomes	47	70
Did not complete program due to medical, behavioral, or situational reasons	11	16
Completed program without demonstrated benefit	1	1.5
Referred to outpatient physical therapy or psychiatric services (outcomes to be determined)	3	4
Total other outcomes	15	21.5
Client could not be reached	5	7
Client has moved out of state	1	1.5
Total not reported	6	8.5

Table 5. CORE Outcomes (February 1984–June 1985)

	Closed Cases	
	Number	Percent
Returned to work	6	38
Accepted into education or job training program	5	31
Doing volunteer work	0	0
Deinstitutionalized and independent in activities of daily living (ADL)	0	0
Report improved quality of life within home and community	3	19
Entered independent living situation	0	0
Total positive outcomes	14	88
Did not complete program due to medical, behavioral, or situational reasons	1	6
Completed program without demonstrated benefit	0	0
Referred to outpatient physical therapy or psychiatric services (outcomes to be determined)	1	6
Total other outcomes	2	12
Client could not be reached	0	0
Client moved out of state	0	0
Total not reported	0	0

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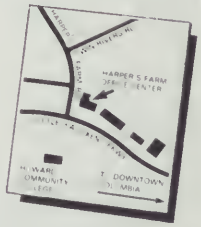
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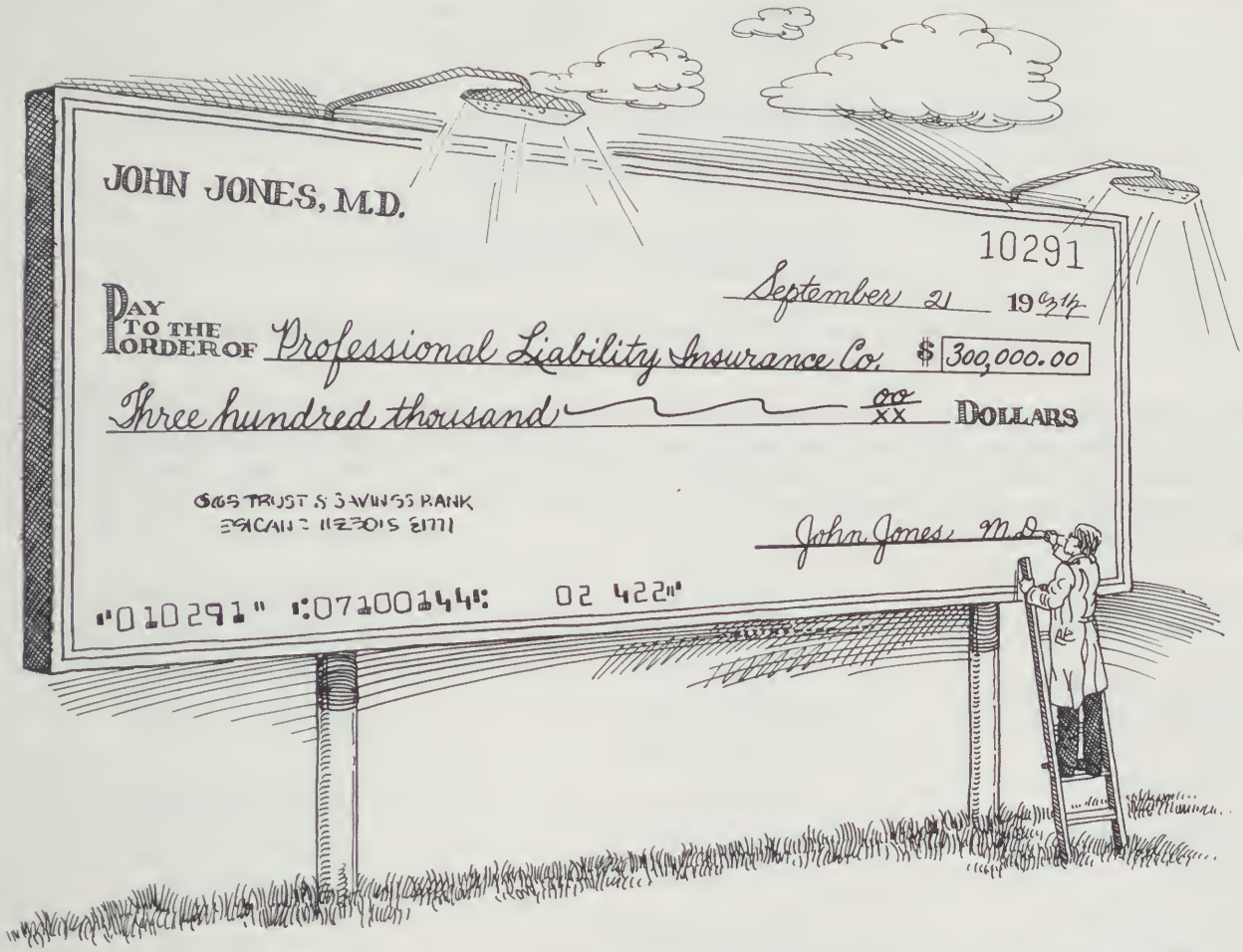
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Medical and Chirurgical Faculty of the State of Maryland

Semiannual Session House of Delegates 316th Meeting

Saturday, September 28, 1985
Minutes: House of Delegates

Faculty Building, 1211 Cathedral Street, Baltimore, MD 21201

The 316th meeting of the House of Delegates of the Medical and Chirurgical Faculty of the State of Maryland was called to order at 2:00 P.M. on Saturday, September 28, 1985 at the Faculty Building, Baltimore, Maryland, The President, J. D. Drinkard, M.D., and Secretary, Bernard S. Karpers, Jr., M.D. being present.

The following delegates (or alternates indicated by an asterisk) were registered as being in attendance, all by county indicated:

Allegany County
Leslie R. Miles, Jr.

Anne Arundel County
Michael J. La Penta
Hilary T. O'Herlihy
Jorge B. Ramirez

Baltimore City
Raymond M. Atkins
James E. Bell
*Joseph I. Berman
Paul Bormel
Vincent DeP. Fitzpatrick
Marion Friedman
Michael G. Hayes
John H. Hirschfeld
John B. MacGibbon
Donald W. Mintzer
*Samuel I. O'Mansky
William F. Renner
Gary L. Rosenberg
*Jerome Ross
Benjamin Rothfeld
Edward L. Suarez-Murias
Thomas E. Van Metre, Jr.
Israel Weiner
*Joseph W. Zebley III

Baltimore County
Andrew A. Alecce
Thomas E. Allen
Sheldon B. Bearman
John W. Buckley
Esther Edery
A. H. Ghiladi
Christopher M. Harvey
Charles F. Hoesch
Paul G. Koukoulas
Herbert J. Levickas
William Reichel
Margaret L. Sherrard
*Anthony F. Stedem
*James Andrew Sumner
*J. Carlton Wich
*Mehdi L. Yeganeh
John F. Strahan

Carroll County
Arthur L. Rudo

Cecil County
Henry J. Farkas
Andrew P. Fridberg

Harford County
Rose Mary H. Bonsack
*Gunther D. Hirsch

Kent County
*Robert W. Farr

Montgomery County
Benjamin Avrunin
Carol L. Bender
Sharon T. Denny
*Donald E. Dillon
*Donald J. Fishman
Edward S. Mehlman
John P. Nasou
*Susan W. Owens
*Angelita D. Sanders
Roy H. Sandstrom

Prince George's County
William B. Hagan
John E. Jeffrey
Reynaldo L. Lee-Llacer
R. Kennedy Skipton
*Frederick H. Wilhelm

St. Mary's County
Mohamed F. Lafeer

Washington County
Robert W. Chambers
Edward W. Ditto III

Wicomico County
*Aubrey C. Smoot

Worcester County
Federico G. Arthes

Council
Albert M. Antlitz
Benjamin Del Carmen
Donald H. Dembo
John M. Dennis
Michael R. Dobridge
J. D. Drinkard
Hubert L. Fiery
Frederick J. Hatem
Bernard S. Karpers, Jr.
Leon E. Kassel
Robert G. Kindred
Donald T. Lewers
George S. Malouf
J. David Nagel
Hiroshi Nakazawa
Charles F. O'Donnell
Roland T. Smoot
Albert J. Strauss
Baltasar B. Velez
Henry N. Wagner, Jr.
Karl H. Weaver
Kennard L. Yaffe
Jose M. Yosuico

Board of Medical Examiners
Arthur T. Keefe, Jr.

Past Presidents
Karl F. Mech

Invocation

Leslie R. Miles MD, Chairman of the Committee on Medicine and Religion, gave the invocation.

Guest Speaker

Carl Sardegna, newly named President of the Maryland Blue Cross and Blue Shield organization, was introduced to the House members, and there was opportunity for questions.

Minutes Approved

The minutes of the meetings of the House of Delegates held April 25 and 27, 1985, not being further corrected, were declared approved as corrected by the Executive Committee, under Special Rule 1.

Council Chairman Reports

On motion of Leon E. Kassel MD, Council Chairman, the following members having received the recommendations of their Component Societies and the Council, were elected to Emeritus Membership in the Faculty:

Emeritus Members

Anne Arundel County
Nelson M. Chitterling MD, Annapolis

Baltimore City
Charles F. Hobelmann MD, Baltimore
Zsigmund J. Toth MD, Baltimore

Montgomery County
Hugh W. Irey MD, Shady Side
M. William Voss MD, Bethesda

Prince George's County
Gideon G. Mercurio MD, Riverdale

St. Mary's County
William D. Boyd MD, Chaptico

Talbot County
Edward D. Delamater MD, Oxford

Wicomico County
William R. Campbell MD, Salisbury

Karl F. Mech, Sr. Resolution

Dr. Kassel, on behalf of the Council, moved adoption of the following resolution honoring Karl F. Mech, Sr., MD which was unanimously adopted by rising vote.

Karl F. Mech, Sr., MD

Whereas, Karl F. Mech, Sr., M.D., one of Maryland's most illustrious surgeons, played an active role in medical affairs since he joined the Medical and Chirurgical Faculty of the State of Maryland in 1940;

Whereas, He continually strove to ensure that the highest quality of medical practice was carried out in Maryland, through service on the Board of Medical Examiners for 17 years; and the Commission of Medical Discipline since its inception until 1985, with continuing service as its Executive Officer; and

Whereas, He also served as Treasurer of the Medical and Chirurgical Faculty for 9 years, and as its President in 1975–76; as Medical Director of Maryland Blue Shield for 22 years; and in countless other capacities, wherever volunteer service was sought; therefore, be it

Resolved, That this House of Delegates wishes to express its highest esteem to a valued colleague for his countless hours of volunteer service, evidenced by his willingness to assume any post for which he was called regardless of the time, energy, and responsibility it would entail; and

Resolved, That this House of Delegates, on Saturday, September 28, 1985, spreads on the records its sincere appreciation to its colleague, Karl F. Mech, Sr., MD for his past service to his profession and community; at the same time, urging his continued service in this area of increasing need.

Council Resolution Adopted

Dr. Kassel, on behalf of the Council, moved adoption of the following policy resolution which received the necessary 2/3 vote for consideration and, after debate, was adopted without dissent:

Whereas, The professional liability insurance crisis in Maryland has reached epidemic proportions resulting in many physicians retiring from practice or restricting their practice categories;

Whereas, Physicians are forced to practice defensive medicine resulting in several million dollars a year being added to health care costs; and

Whereas, The Medical and Chirurgical Faculty has a moral responsibility to ensure patients have access to needed medical care and to ensure the highest quality of care is provided; therefore, be it

Resolved, That the Medical and Chirurgical Faculty of the State of Maryland in concert with the component societies embark upon a public awareness campaign to amend the medical malpractice laws in the State of Maryland, to warn the public of the dangers if the situation is not corrected; and

Resolved, That the House of Delegates authorize a voluntary contribution of one hundred dollars per active member be made to fund this campaign.

Treasurer's Report

Jose M. Yosuico MD, Faculty Treasurer, read the certificate of Wooden and Benson, CPAs, as to the accuracy of the Faculty's books and records for the 1984 calendar year, and an opportunity was given for questions. The House, by unanimous consent, approved the auditor's certification.

1984–1985 Committee Reports

The following 1984–1985 Committee reports having been distributed in writing to all members for information, an opportunity was afforded to raise questions or make comments.

Report of the Delegates to the American Medical Association—Charles F. O'Donnell MD, Albert M. An-

tlitz MD, Manning W. Alden MD, Donald T. Lewers MD, George S. Malouf MD, Roland T. Smoot MD (Interim Meeting, December 2–5, 1984)
Ad Hoc Building Committee—George S. Malouf MD, Chairman
Committee on Alcoholism—John H. Hirschfeld MD, Abraham M. Schneidmuhl MD
Committee on Continuing Medical Education Review—Jonathan M. Sutton MD, Chairman
Committee on Cost Effective Medical Care—Peter E. Dans MD, Chairman
Curator—E. David Weinberg MD
Committee on Drugs—Stephen A. Hirsch MD, Chairman
Committee on Emergency Medical Services—John B. DeHoff MD, Chairman
Committee on Emotional Health—Gary W. Nyman MD, Chairman
Executive Director—John Sargeant
Finance Committee—Jose M. Yosuico MD, Chairman
Finney Fund Committee
Report of AMA-ERF Committee of the Auxiliary—Mrs. Elizabeth Linhardt, Chairman
Report of the Auxiliary—Mrs. Mildred S. Taylor
Hearing and Vision Early Screening (HAVES) Program—George C. Alderman MD, President (no report)
Health Manpower and Planning Committee—James T. Estes MD, Chairman
Ad Hoc Committee on Home Health Care—J. D. Drinkard MD, Chairman (no report)
Committee on Hospital Medical Staffs—J. David Nagel MD, Chairman
Legislative Committee—Jose Martinez MD, Chairman
Liaison Committee with Department of Health and Mental Hygiene—Karl M. Green MD, Chairman
Liaison Committee with Third Party Carriers—Paul Bormel MD, Chairman
Library and History Committee
Long Term Care and Geriatrics Committee—Edmund G. Beacham MD, Chairman
Maryland Medical Political Action Committee—Mrs. Helen Boyer, Chairman
Maryland Medical Journal—James G. Zimmerly MD, Editor, Victor R. Hrehorovich MD, Associate Editor
Med-Chi Insurance Fund—W. Kenneth Mansfield MD, Chairman
Medical Annals of Maryland—Henry B. Wilson MD, Chairman (no report)
Medicine and Religion Committee—Leslie R. Miles, Jr., MD, Chairman
Medicolegal Committee—Donald M. Barrick, MD
Occupational Health Committee—Michael K. Spodak MD, Chairman
Peer Review Committee—Walter J. Alt MD, Chairman
Physician/Patient Relations Committee—Lois E. Wehren MD, Chairman
Committee on Physician Rehabilitation—Joseph F. Chambers MD, Chairman
Policy and Planning Committee—(no report)
Committee on Preventive Medicine and Public Health—Vincent D. Fitzpatrick MD, Chairman
Ad Hoc Committee on Private Practice—Seymour Weiner MD, Chairman (no report)
Committee on Professional Ethics—Louis C. Breschi MD, Chairman
Public Relations Committee—James E. Bell MD, Chairman
Committee on Scientific Activity—Morton I. Rapoport MD, Chairman
Secretary—Bernard S. Karpers, Jr., MD
Treasurer—Jose M. Yosuico MD
Committee on Utilization and Quality Control Peer Review—Leon E. Kassel MD, Chairman (no report)

Motion Adopted

On motion of Michael Hayes MD, Chairman of the Committee on Physician Rehabilitation, the following motion was, after debate, adopted by a vote greater than two-thirds:

To amend the resolution adopted at the last session, relating to an assessment, by adding the following resolving clause:

Resolved, that the half-time coordinator position be expanded to a full-time program director position as a regular full-time staff member of Med-Chi after January 1, 1986 if, in the judgment of the Executive Committee, adequate funds are available.

Memorial Resolution

The Secretary reported the following resolution, which was adopted unanimously by the House:

Elliott R. Fishel MD, 1919–1985

Whereas, Elliott R. Fishel MD, President of the Baltimore City Medical Society, died suddenly on Sunday, May 12, 1985;

Whereas, Dr. Fishel was a member of the Baltimore City Medical Society and the Medical and Chirurgical Faculty from 1952 until his untimely death;

Whereas, Dr. Fishel served the medical community and the public in many capacities, including service as a member of the BCMS and Med-Chi Peer Review committees, chairman of the BCMS Peer Review Committee, member and chairman of the Med-Chi Medicolegal Committee, Delegate to the Med-Chi House of Delegates, member of the BCMS Board of Directors, Vice President of the BCMS, and ultimately its President;

Whereas, Dr. Fishel was a devoted practitioner of surgery, holding several positions and offices in the Maryland Chapter, American College of Surgeons;

Whereas, Dr. Fishel was born, reared, educated, and practiced in the City of Baltimore and devoted his life to serving its citizens; and

Whereas, Elliott R. Fishel MD will be deeply missed by his colleagues, his patients, his many friends, and his loving family; therefore, be it

Resolved, That this House of Delegates in session on Saturday, September 28, 1985 adopts this memorial resolution in honor of Elliott R. Fishel, M.D. and sends its deepest sympathy to his wife, Dorothy, and to his children and grandchildren.

Maryland Foundation for Health Care Elections

The Secretary read the nominations submitted for election to the Board of Directors of the Maryland Foundation for Health Care. Nominations were made from the floor, in certain cases where nominees had not been submitted.

There being no contest for any position, the following were elected by voice vote:

Baltimore City
Ian R. Anderson MD, GS (1988)
Allan D. Jensen MD, OPH (1988)
Stephen M. Busky MD, U (1988)
Albert Nahum MD, IM (1988)
Baltimore County
John H. Hebb MD, OB/GYN (1988)
Montgomery County
Martin H. Eichler MD, GS (1988)
John P. Nasou MD, IM (1988)
Southern District
Sergio Alvarez MD, GS, Anne Arundel County (1988)
Eastern District
Louis H. Himes, II, MD, EM, Wicomico County (1986)
Aubrey C. Smoot MD, OTO, Wicomico County (1987)
Western District
Gary A. Fleming MD, PD, Allegany County (1987)

Bylaws Committee Report

Reynaldo Lee-Llacer, M.D., Chairman of the Bylaws Committee, moved adoption of the following bylaw amendment which, after debate, was adopted by the required two-thirds vote:

PRO Monitoring Committee

Amend Article XI, Section 32, by substituting the following:

The PRO MONITORING COMMITTEE shall be appointed by the President. The President shall designate the chairman. All members shall be chosen for their knowledge, experience, and interest in the activities of the Professional Review Organizations. The committee shall act as an analytical group to review the effect of programs carried out by the Maryland Foundation for Health Care with respect to the cost and quality of medical care. The committee will also assist in providing informational and educational activities to such groups and individuals as may be appropriate, and advise other health care agencies on the issues of medical care quality.

Committee on Alcoholism and Chemical Dependency

Dr. Lee-Llacer, on behalf of the Bylaws Committee, moved adoption of the following bylaw amendment which, after debate, received the required 2/3 vote and was adopted as follows:

Amend Article XI, Section 1, by substituting the following:
A COMMITTEE ON ALCOHOLISM AND CHEMICAL DEPENDENCY of at least five members appointed annually by the President shall work toward educating the public and the membership with respect to alcoholism and chemical dependency as illnesses; present scientific information to physicians relative to alcoholism and chemical dependency; and offer its services to hospital medical staffs in an attempt to have such members understand alcoholism and chemical dependencies. The committee may cooperate with government and private agencies working in the field of alcoholism and chemical dependency and invite the attendance of physicians and nonphysician members of such agencies to work with the committee on a nonvoting basis.

Committee on COMER

Dr. Lee-Llacer, on behalf of the Bylaws Committee, moved adoption of the following bylaw amendment, which was adopted without dissent:

Amend Article XI, Section 3 (Committee on Continuing Medical Education Review) by striking out the words "AMA Liaison Committee on Continuing Medical Education" and inserting the words "Accreditation Council for Continuing Medical Education."

Committee on Physician Assistants

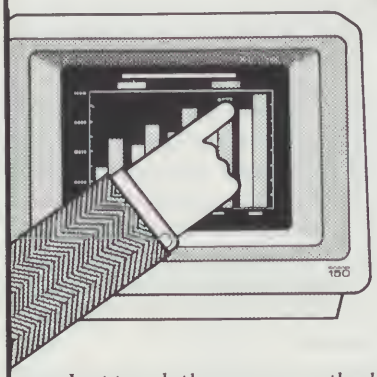
Dr. Lee-Llacer, on behalf of the Bylaws Committee, moved adoption of the following bylaw amendment which, after debate and amendment, was adopted by the required two-thirds vote as follows:

Amend Article XI (Committees) by inserting after Section 23 the following new Section 24 (subsequent sections being automatically redesignated):

Section 24. A COMMITTEE ON PHYSICIAN ASSISTANTS of at least three members shall be appointed annually by the President. It shall elect its own chairman. The Maryland Academy of Physician Assistants (MAPA) shall submit names of Physician Assistants to the President for consideration as ex-officio members of this committee. At least one Physician Assistant shall represent the MAPA Board of Directors. In addition, the Legislative Aide for MAPA shall represent it as an ex-officio member. Physician nominees shall be submitted by MAPA to the President for consideration. The physicians should currently supervise, have supervised in the past, or work or have worked in association with Physician Assistants. Appointments to this committee shall exclude persons currently serving on the Physician Assistant Advisory Committee to the Board of Medical Examiners. The committee shall have as its duty the monitoring of developments in the Physician Assistant profession at local, state, and national levels and the dissemination of such information as it obtains to the House of Delegates, appropriate Faculty committees, component societies and individual members of the Faculty. The committee may make recommendations to the Faculty's governing bodies, appropriate Faculty committees and component societies.

Amendments Adopted

Dr. Lee-Llacer, on behalf of the Bylaws Committee, moved adoption of the following bylaw amendment,



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HEWLETT PACKARD

which was adopted by unanimous consent:

Amend Article VII (Council) Section 4, by striking out "three" before the word "members" and inserting "seven."

Dr. Lee-Llacer, on behalf of the Bylaws Committee, moved adoption of the following bylaw amendment, which was adopted by unanimous consent:

Amend Article III (Finance) Section 7, by striking out "sixty (60) days" and inserting "thirty (30) days."

No Action on Previous Resolutions

The Secretary read a staff report on a review of previously adopted policy resolutions. No action was required because the purposes have been accomplished. These resolutions were:

7A/75 and 8A/75.

Report on Resolution 1A/85

The report on Resolution 1A/85 by the Maryland Foundation for Health Care, having been distributed to all members prior to the meeting, was received for information only.

Ad Hoc Building Committee Report

George S. Malouf MD, Chairman, gave a brief report on the progress of renovation of School #49 and advised the House of the need for additional funds to complete the renovation.

Auxiliary Report

Mrs. Kathleen S. Karpers, Jr., Auxiliary President, gave an update on the activities of the Auxiliary.

There being no further business, the meeting was, by unanimous consent, adjourned *sine die* at 3:35 p.m.

BERNARD S. KARPERS, JR., **MD**
SECRETARY

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Commission on Medical Discipline
Annual Report
July 1, 1984–June 30, 1985

Mr. President and Members of the House of Delegates:

A. Formal Disciplinary Action	FY 1985	FY 1984	Change (percent)
Reprimand	0	2	
Revocation	7	6	
Suspension	0	2	
Probation	0	3	
Forced resignation	0	0	
Emergency suspension	3	1	
Reinstatement	3	12	
Denial of reinstatement	1	1	
Probation termination	7	13	
Modification of probation	0	0	
Not guilty	0	1	
Total	21	41	−50
(Orders, Consent Orders, Disposition Agreement, Memorandums)			
B. Informal Disciplinary Actions			
Improper billing or overcharging	72	81	
Failure to forward records	1	5	
Communication problems	26	31	
Administrative errors	0	2	
Abandonment	0	0	
Patient care	30	15	
Miscellaneous	0	17	
Total	129	151	−15
C. Total Disciplinary Actions	150*	192	−22
D. Disciplinary Action Rates			
By Active-Licensed Physicians	7/1000	4/1000	
By New Complaints Received	42%	49%	
E. Detail by Formal Action Type			
Revocation: 7			
Professional and/or mental incompetence	4	2	
Conviction of a crime of moral turpitude	2	2	
Drug dependency	0	0	
Immoral conduct	0	0	
Action by other jurisdiction	1	2	
Violation of probation	0	0	
Suspension: 0			
Professional and/or mental incompetence	0	0	
Conviction of a crime of moral turpitude	0	2	
Violation of probation	0	0	
Action by other jurisdiction	0	0	
Immoral conduct	0	0	
Reprimand: 0			
Professional and/or mental incompetence	0	0	
Conviction of a crime of moral turpitude	0	0	
Immoral conduct	0	0	
Filing false statements to collect fees	0	1	
Action by other jurisdiction	0	1	
Forced Resignation: 0			
Professional and/or mental incompetence	0	0	
Emergency Suspension: 3			
Drug dependency	0	0	
Improper prescribing practices	2	0	
Mental incompetence	1	1	
Not Guilty: 0	0	1	

* Disciplinary Action per every 140 doctors

A. Formal Disciplinary Action	FY 1985	FY 1984	Change (percent)
Reprimand	0	2	
F. Workload			
New complaints	366	397	−8.5
Total cases under jurisdiction	623	758	−22
Cases completed	385	501	−30
Cases currently active	238	251	−7
Under investigation	211	235	−9
Awaiting formal action	27	22	+23
Post-order surveillance	32	20	+40
Missing respondents	0	0	
Meetings scheduled	30	36	
Meetings held	27	37	
Attendance rate	69%	72%	
Formal hearings	21	11	
Informal meetings	25	31	
Prehearing conferences	9	10	

G. Commision Membership, FY 1985	Term Expires FY
Rose Mary Bonsack MD	June 30, 1989
Thomas C. Cimonetti MD	June 30, 1987
Claude Hill MD	June 30, 1988
Leon E. Kassel MD	June 30, 1986
Reynaldo Lee-Llacer MD	June 30, 1988
Donald T. Lewers MD	June 30, 1986
Margaret F. McKean	June 30, 1986
Karl F. Mech MD	June 30, 1986
Christine J. Moore	June 30, 1988
Hilary T. O'Herlihy MD	June 30, 1986
Ronald J. Taylor MD	June 30, 1987
Merton White MD	June 30, 1986

H. Commission Counsel, FY 1985

General Counsel:
- Varda Fink, Assistant Attorney General
- Joseph McCurdy, Assistant Attorney General

Administrative Prosecutors:
- Barbara Foster, Assistant Attorney General
- Alice Ike, Jr., Assistant Attorney General
- Susan Feldman, Assistant Attorney General
- James Casey, Assistant Attorney General

I. Legislation of Interest

S.B. 390—Physicians—Licensing Incompetency

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Chairman

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	Steven Brand, MD	*301-662-4010*
January	*Augustus Brown IV, Esq.*	*301-838-5500*
	Edward Cornfeld, MD	*301-428-0900*

Delegates to the AMA House of Delegates

Annual Meeting June 14–20, 1985

Mr. President and Members of the House of Delegates:

The following issues highlight the Annual Meeting of 1985 in Chicago. The big topics were malpractice and reimbursement programs. Running third but equally important was funding of graduate medical education as well as physician supply. There was nothing as striking or controversial as a ban on boxing, but a great deal more was done at this meeting that will have a long-term effect on the quality of health care in this country.

Reference Committee on Amendments to Constitution and Bylaws

Little came from this committee in 1985. There were some minor housekeeping changes. The following highlights are noted: (1) The name of the Judicial Council was changed to the Council on Ethical and Judicial Affairs. (2) The American Academy of Otolaryngic Allergy was admitted to membership and the American Society of Clinical Oncology was not. (3) The Judicial Council's "second opinion" program's report was adopted. (4) Blood doping by American athletes is to be studied in detail by the Council on Scientific Affairs. (5) The AMA reaffirmed its position that the welfare of the patient must be placed above the financial interest of the physician.

Reference Committee A: Insurance and Medical Service

Several interesting factors appeared in this Reference Committee: (1) Reviews of dialysis as well as acute arthritis rehabilitation guidelines were referred to the Board for further study and will go to the Council on Medical Service and possibly the Scientific Affairs. (2) A complex question was raised regarding payment for services for both diagnostic and therapeutic surgical procedures. It was thought there should be some differentiation and was referred to the Board for further study. (3) There was much discussion regarding home health service abuse. A resolution was adopted calling on the nation's physicians to carefully review orders and to monitor home health service agencies, since in many areas of the country there has been a great deal of abuse. (4) Resolution 85 recommended that AMA seek changes in the Medicare guidelines to provide for preventive medicine services. Although the Reference Committee opposed this, the House adopted it. (5) New York believes the Medicare people should change the frequency of nursing home visits. This a major problem there and elsewhere. Because of the complexity of the problem, it was referred to the Board for further study. (6) Resolution 87 requiring HCFA consider reimbursement for laboratory interpretation and home health care was amended and adopted. (7) Resolution 38 requiring that AMA work with organizations of the aged to insure their members are aware of the pros and cons of the Medicare HMO enrollment was amended and adopted. (8) A major study will be done of preadmission review and a prior authorization program. (9) The AMA also is to work with insurers to ensure they inform their insureds of the restrictions and conditions of prior authorizations of services. It is the responsibility of the insured to properly notify a physician of any preauthorization requirements. (10) Report A of the Council on the Medical Service is a detailed report on the amount of uncompensated care provided by physicians and on the type of patients receiving such care. This is a very important report and should be reviewed.

Reference Committee B: Legislation

This Committee report covered the malpractice crisis. (1) Report II of the Board of Trustees was adopted. It states: if a physician is required to treat a patient for a fee fixed by the government and that physician accepts those fees, the physician is to be indemnified in the event of professional liability arising out of such treatment. Any defense costs or awards arising from such a suit would be paid by the appropriate government entity. This obviously requires legislative change and will never occur, but it is interesting that the AMA will take such a position. (2) The malpractice crisis, discussed at great length, largely centered on the federal incentive program and model legislation. It is obvious that the AMA is working hard in this direction. (3) The Resolution was accepted and amended stating that where immunization is required, any injuries must be compensated by the government that required the immunization. (4) Opposition to the fee freeze was continued; AMA is to work with HCFA on reevaluating data and methodology used in calculating customary profiles and prevailing screens.

Reference Committee C: Medical Education

Graduate medical education funding is at a crisis stage, and the AMA is working on this. (1) In many areas of this country residency positions are for sale; this problem is being studied by the Board. (2) Physician supply and physician manpower is becoming a more critical issue. The AMA, as a result of Resolution 47, has formed a task force to study this on a national basis and encourages that it be studied locally. All data obtained will be available to the states at cost.

Reference Committee D: Hospitals and Medical Facilities

Primary subinterests of this committee are: (1) Virginia advocates a uniform laboratory standard for the country. Our problem in Maryland has been referred to the Board of Trustees. (2) There was discussion of organ donor and transplant policies with an attempt to get some uniform system or, at the least, some statement in the bylaws of each hospital. (3) The AMA will push for hospital ethics committees. (4) The report from the Board of Trustees regarding hospital medical staff joint ventures was accepted and is to be made available and widely disseminated soon. (5) A recommendation is being made to develop model state legislation that would provide civil immunity to county, state, and medical specialty societies for peer review. Apparently, doctors are exempt, but societies are not.

(6) Specialty board recognition by the American Board of Medical Specialties received a great deal of discussion. Other groups such as the chiropractors and osteopaths have developed a number of "boards" that require minimal certification. Since the JCAH states that boards are important in determining credentials, these bodies have made boards so available that many hospitals have to take doctors who have substandard boards. (7) In many areas economically motivated patient transfers have become a problem; the AMA is opposed to such actions. (8) One important recommendation is that guidelines be created for outpatient surgery and same-day admission. Hospitals should redefine "hospital day." Basically, if someone is in the hospital at midnight, it counts as an entire day. It was suggested the hospital day be changed so that if a patient were to come in at 8 or 9 p.m. to be bedded down for either surgery of testing the next morning and were to leave before a 24-hour period elapsed, it would not be counted as an entire "hospital day." This would help the elderly and individuals who live alone and would permit same-day surgery in this group. (9) It was pointed out that a hospital administrator is important at medical staff executive committees. Many hospitals consider the administrator as "ex officio," believing he/she can be asked to leave a meeting if executive session is called. However, by legal definition that individual has all the rights, privileges, and responsibilities of the committee to which he/she is ex officio. A member on a committee in ex officio status cannot be asked to leave executive session. An ex officio member also has votes. A resolution was passed to recommend that hospitals look at this carefully.

Reference Committee E: Scientific and Public Health

The Council on Scientific Affairs issues many important documents each year. These issues were heard this year: (1) Mentally ill homeless will be studied in association with the American Psychiatric Association and other groups. (2) The Board is looking carefully at AIDS, and the Council on Scientific Affairs will be developing a statement. (3) The Council on Scientific Affairs' report on alcohol and the driver was accepted. This supports the position that a 0.05 blood alcohol content is legal/illegal for driving, dropping the level significantly. Studies have shown that at this level and above, the accident ratio and injury ratio is increased at least three times. (4) A strong stance on antismoking and on ending tobacco subsidies was taken and will be continued. (5) AIDS and HTLV 3 antibody testing have been referred to the Board primarily because the AMA is very sensitive to the releasing of this information and the requirement that any individual who is tested and is positive must be informed of that positive test. (6) Medical schools will be encouraged to make available Hepatitis B vaccine to physicians in training. (7) Drug education is to be carried out with the NCAA and is to include all other intercollegiate groups.

Reference Committee F: Board of Trustees

The auditor's report and budget were accepted. After lengthy discussion AMA dues were increased by $45. It is obvious that AMA dues would not have to be increased if membership could be increased. The membership is increasing, but expenses are also increasing. Mailing costs alone went up $1.3 million last year, and activities in Washington are expensive. While many people went to the meeting opposed to an AMA dues increase because they thought it would adversely affect membership, there was an overwhelming vote of approval for the increase. (1) It was pointed out that a public awareness campaign will stress that the physician and organized medicine are really the patient's best advocate. (2) A research and faculty section has been recommended by the long-range planning committee. A committee will be established to increase the membership of medical researchers and medical school faculty in AMA. This a very important committee and one in which Maryland needs to play a major role.

Reference Committee G: Miscellaneous

The report on the national relative value scale from the Board was adopted. Exactly where this is going no one knows. There was major support for an indemnity payment system, although there was much discussion. Refer to Resolution 65, under Reference Committee G. This says that the patient is responsible for his/her bill. (1) The Board of Trustees was instructed to interact with the AARP regarding balanced billing and the importance of the changes occurring in medicine today. (2) The AMA voted to support legislation amending the current federal law so that employers must offer multiple options for health-care benefits to employees and that fee for service be one of those options. (3) The AMA will look carefully at the Georgia experiment with IPAs. (4) It is recommended that PPO terminology be changed to "contract physician provider (CPP) rather than preferred provider. Probably the term "contract provider organization" will be used in lieu of "preferred provider organization." (However, PPO may be too ingrained to change it to CPO.) (5) Resolution 111 was in response to an alternate delivery system by the Volunteer Hospital Association of America and the Teamsters. AMA has been instructed to review and to inform physicians of the proposed terms of this arrangement. (6) A controversial issue was DRGs for the federal health programs. The states where DRGs are in place think any federal programs also should be subject to the same DRGs. We favor the DRGs for the federal health programs. This subject was referred to the Board. (7) The AMA has a policy encouraging and supporting the testing of innovative medical reimbursement systems to be implemented only after they have appropriate and adequate testing. They should assure the highest quality care to patients. (8) Support for inner-city hospitals was emphasized. (9) It was recommended that work be done to see that the PROs have an appeal process that can be initiated by a physician. Resolution 51 was adopted: if third-party payers or government units retrospectively deny hospitalization, they should reimburse the hospital at least to the extent that the services would have been covered as an outpatient. This interesting concept may not go far. Reference Committee AA and Committee H had to do with corporal punishment in schools as well as alcohol ad-

vertising. The issue of alcohol and alcoholic advertising has been referred back to the Board. (10) This is also the one where Resolution 8 was referred to the Board for the study of the manufacturer's obligation to motorcycle safety. This was expanded to cover three-wheeled vehicles. The use of seatbelts was strongly recommended; where mandatory use of seatbelts has been indicated the costs saved and lives saved have been tremendous. (11) There was much discussion on the opposition to apartheid and other areas of discrimination. This came out as a positive statement but the wording was cautious.

Delegates:

CHARLES F. O'DONNELL **MD, Chairman**
ALBERT M. ANTLITZ **MD, Co-Chairman**
ROLAND T. SMOOT **MD**
DONALD T. LEWERS **MD**
GEORGE S. MALOUF **MD**
MICHAEL R. DOBRIDGE **MD**

Alternates:

MANNING W. ALDEN **MD**
J. ROY GUYTHER **MD**
IRVING A. COHEN **MD (Resident)**
JEFFREY H. HELLMAN **(Student)**
JOHN H. HEBB **MD**
HENRY N. WAGNER, JR., **MD**

MMPAC Board of Directors

Mr. President and Members of the House of Delegates:

This past year has been active for the Maryland Medical Political Action Committee.

The Board of Directors met every other month with a full agenda at each meeting. Many hours were spent interviewing candidates who requested monies from PAC. These interviews were conducted to assess political philosophy, ideology, and attitudes toward the problems and needs of the medical profession. The Board remained remarkably nonpartisan, choosing to support candidates from both major political parties in nearly equal number. Every candidate supported by MMPAC was elected.

The Semiannual luncheon meeting in Ocean City was a sellout. Former Governor Marvin Mandel spoke on "The Importance of your Participation in Elections: Why Every Vote Counts."

While overall membership was down slightly (this was not unique to the State of Maryland), sustaining membership continued to grow and surpassed our tremendous growth of the previous year.

At the MMPAC Luncheon at Annual Meeting, Andrew Sumner MD, Baltimore County, was elected to serve as Chairman for the next term. Under his leadership, I am confident MMPAC will continue to be responsive and productive.

Officers and Board Members have given generously of their time and expertise and have been faithful in attending meetings. Med-Chi staff has given long hours of hard work and devotion. To all these individuals, the Chairman is most grateful.

Two years ago when I accepted the responsibility of chairing this committee, it was not without apprehension. But the apprehension gave way to challenge, and the challenge has been most rewarding. I thank the MMPAC membership for giving me the honor of becoming the first nonphysician to chair this important committee.

I leave you with this thought: Physicians, get involved. Become politically knowledgeable. Get to know your legislators. Like it or not, the freedoms of *your* profession depend, in great part, on *your* political involvement.

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Include in the manuscript the concise title, full name of the author (or authors) with highest degree, academic and professional titles, affiliations, and any institutional or other credits.

An introductory synopsis/abstract of approximatey 100–150 words is required.

Tables are to be typed on separate sheets of paper, numbered, and have a brief descriptive title. The Editor reserves the right to edit tables. Be sure that statistics are consistent in both tables and text.

References are limited to those citations noted in the text. References are to be typed double-spaced and numbered consecutively as they appear in text. They will be examined critically at the time of review and must be kept to a minimum. The number of references is generally limited to 20 in major contributions and fewer in shorter articles. Exceptions may be made if appropriate in the opinion of the reviewing editor. Personal communications and unpublished data should not be included. The following are necessary: names of all authors, complete title of article cited (lower case), name of journal abbreviated according to *Index Medicus*, volume number, first and last page numbers, and year of publication. For more extenisve information about preparing medical articles for publication, the editors suggest the International Committee of Medical Journal Editors: Uniform requirements for manuscripts submitted to biomedical journals. The complete document is available in the June 1982 issue of the *Annals of Internal Medicine*.

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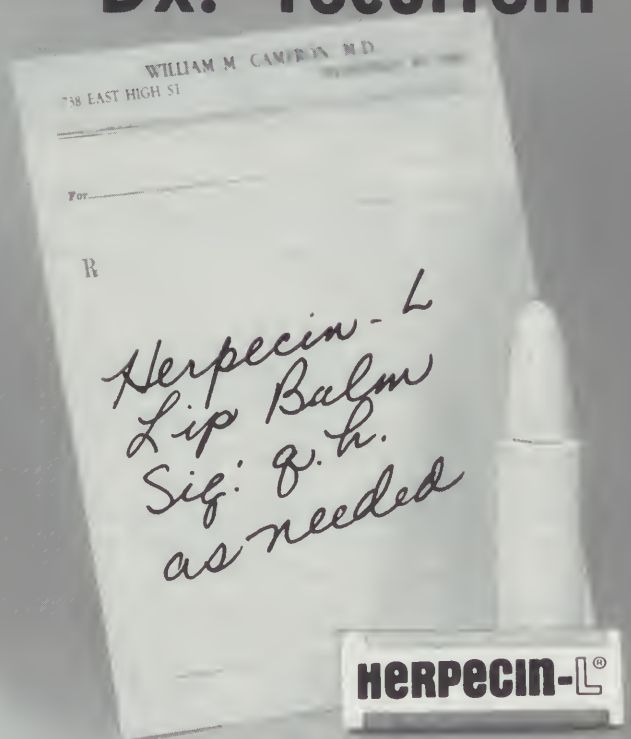
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Members in the News

David A. Blass MD has been appointed full-time Director of the Medical Intensive Care Unit at St. Agnes Hospital. Dr. Blass received his B.S. degree from the University of Maryland College Park, and his medical degree from the University of Maryland School of Medicine. He served an internship and residency in internal medicine at Washington Hospital Center, and a fellowship in pulmonary diseases at George Washington University Medical Center, both located in Washington, DC.

• • •

Gary Cohen MD has been appointed coordinator of the oncology program at Sinai Hospital, Baltimore. Dr. Cohen will be directing all aspects of cancer care and developing new programs to improve the care and comfort of cancer patients at Sinai.

Dr. Cohen earned his undergraduate degree at Duke University and his medical degree at the University of Maryland. He served his residency at the State University of New York at Buffalo and his fellowships in oncology and hematology at the Sidney Farber Cancer Institute at the Harvard Medical School. Following his fellowship, he was appointed to the staff of the Cancer Institute and Brigham and Women's Hospital in Boston and was on the full-time faculty at Harvard in a teaching and research capacity.

William Reichel MD, Chairman of the Department of Family Practice at Franklin Square Hospital, has been awarded the prestigious Malford Thewlis Award by the American Geriatrics Society for outstanding contributions to the Society. Dr. Reichel is a past-president of the American Geriatrics Society and sat as a member of their Board from 1971 to 1984.

Dr. Reichel recently completed the Chairmanship of the Governor's Task Force on Alzheimer's Disease and Related Disorders, which presented its findings to the Chief Executive in June.

• • •

New Medical Staff Officers at Franklin Square

Louis Breschi MD has been elected President of the Franklin Square Hospital Medical Staff. Dr. Breschi, a urologist, joined the medical staff in 1972. A Towson resident, he is a graduate of the University of Maryland Medical School.

Sheldon Bearman MD, a radiologist, was elected Vice-President, having served as Secretary-Treasurer during the past year. **Robert Kasper** MD, an ophthalmologist, was elected Secretary-Treasurer.

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Jan 24–26 Current Controversies and Techniques in Congenital Heart Surgery. Baltimore Convention Center. Fee: $225, 12.5 AMA Cat I credits.

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Miscellaneous Meetings

Feb 21–23 1986 Annual Meeting and Scientific Session Virginia Chapter, AAP and The Virginia Pediatric Society, Williamsburg Conference Center, Colonial Williamsburg, VA. CME designation: 12 PREP hours and 15 AMA Cat I hours. Info: 804-643-8130.

March 5, 12, 19 Psychoanalytic Perspectives on Ulcerative Colitis at the Baltimore-DC Psychoanalytic Institute, 821 N. Charles St., Baltimore. First in a series of presentations on Classical Psychosomatic Disorders. 8–9:30 p.m.; 4.5 AMA Cat I credits for program. Mar 5: Review of Important Literature; Mar 12: Implications for Medical Management; Mar 19: Participants opportunity to discuss cases. Info/registration 301-727-1740.

May 8–10 Alumni Crab Feast, University of Maryland School of Medicine, 7–10 p.m. Students Common, MSTF. Info: J. Thompson 301-528-7454.

May 10 Alumni Reception and Dinner Dance, at the Sheraton Inner Harbor, University of Maryland School of Medicine. Info: J. Thompson 301-528-7454.

May 27–31 Fifteenth Annual SCCM Educational and Scientific Symposium, Washington, DC. Fee: Nonmember physicians $375, nurses and therapists $270, member physicians $275, nurses and therapists $225; approx 40 Cat I credits. Info: T. Schultz 714-870-5243.

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The Johns Hopkins Medical Institution

All courses at the Turner Auditorium Building unless otherwise indicated. Sponsored Continued Education Activities for 1985–86. Info: Office of Continuing Education, 720 Rutland Ave., Turner Auditorium, Baltimore, MD 21205 (301-955-5880).

Jan 17 Macular Diseases: Current Concepts and Practical Management. Fee: $160, $80 (those in training with letter verifying status); 8 AMA Cat I credits. Info: P. Macedonia 301-955-6046.

Feb 20–21 Diagnosis and Treatment of Sex Disorders. Hours of instruction: 16.

Feb 24–25 Applied Ethics: Caring for the Mentally Impaired Elderly. Fee: two days $150; one day $100. Appropriate credits applied for. Info: P. Macedonia 301-955-6085.

Feb 27–Mar 1 Symposium on Dysphagia. Hours of instruction: 17.

Mar 3–5 Obesity and Other Eating Disorders. Hours of instruction: 20.

Mar 6–7 Asbestos. Hours of instruction to be announced.

Mar 10–12 The Spectrum of Developmental Disabilities VIII. Issues of Diagnosis, Evaluation, Habilitation, and Research of the Preschool and School Age Child. Hours of instruction: 20.

Mar 13–14 Brain Receptors: Images and Ideas. Hours of instruction: 15.

Mar 14 Ocular Histoplasmosis Syndrome. Columbia, Maryland. Hours of instruction: 8.

Mar 21 Computers in Ophthalmology. Hours of instruction to be announced.

Mar 22–23 Hemodynamic Monitoring/Patient Care and Pulmonary Artery Catheterization. Hours of instruction: 12.5.

Mar 24–26 Critical Care Medicine. Hours of instruction: 24.

Apr 3–4 Diagnosis and Treatment of Neoplastic Disorders. Hours of instruction: 45.

Apr 7–12 Pediatric Trends 1986. Fee: $500; 45 AMA and 45 PREP credits. Info. Course Coordinator 301-955-5880.

Apr 14–15 *In Vitro* Toxicology—Approaches to Validation. Fee: $225 before Mar 1, $275 thereafter; 15 AMA Cat I credits and 1.5 CEU pending. Info: J. Ryan 301-955-6046.

Apr 28–30 Interventional Radiology and DSA. Fee $325 physicians; $175 residents, nurses, technologists; 25 AMA Cat I credits; ECE by ASRT. Info: C. Kearney 301-955-3168.

The Department of Radiology and Radiological Science offers several courses in abdominal and obstetrical ultrasound: Courses scheduled 1/6/86–12/8/86. Info: J. Mosmiller 301-955-8450.

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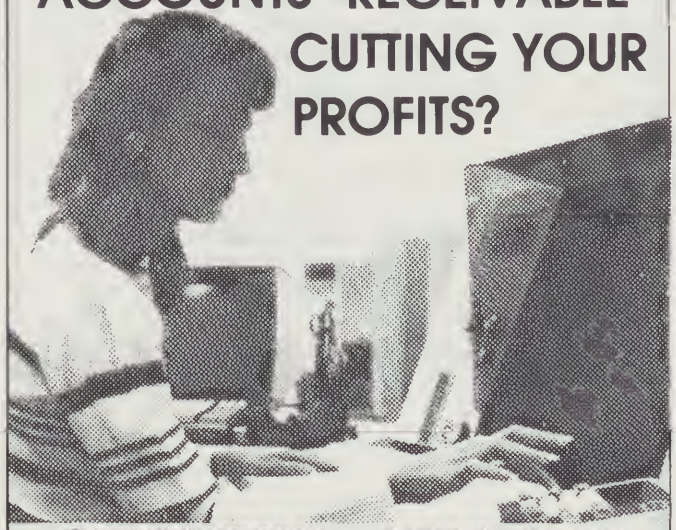
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McClinton MA; Wright S. High-pressure tool injection injuries. 289.
ACQUIRED IMMUNODEFICIENCY SYNDROME
Berger R. Cost analysis of AIDS cases in Maryland. 1173.
Maryland. Office of Disease Control and Epidemiology. Newsletter. 31, 223, 563, 745, 853.
Adams JE. see Waurin JL.
ADENOCARCINOMA—THERAPY
Elias, EG. Management of primary adenocarcinoma of the large bowel. 349.
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Allinson EE. Members in the news. 701.
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Maryland Commission on Hereditary Disorders. Guidelines: screening for neural tube defects in the fetus. 586.
Alvarez S. Members in the news. 190.
AMA's Survey and Opinion Briefs.
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The elderly and medical care in America: their own evaluation of quality, access, and cost. 598.
Patient education, PMIs, and physician opinion. 116.
Physicians' preferences for payment methods. 377.
Public image of physicians revisited. 875.
Public support for malpractice reform. 255.
AMBULATORY CARE
Reed JW. Curriculum in ambulatory care. 281.
AMNIOCENTESIS
Waurin JL; Adams JE; Baramki TA. Parental diagnosis of 45, X/46, XY. 883.
ANAPHYLAXIS
Mueller PG. Emergency treatment of anaphylactoid reactions to radiographic contrast materials. 277.
ANDROGEN ANTAGONISTS
de Bittner MR; Iber F. The use and abuse of cimetidine in a gastroenterology clinic. 359.
Angell FL. Members in the news. 190, 701.
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ANTINEOPLASTIC AGENTS, COMBINED
Elias EG. New drug development program. 1157.
Antlitz AM; Valente CM. Healthy mothers/healthy babies. 971.
see also Campbell JL.
see also Valente CM.
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Covi L. What to treat: Anxiety or depression? 859.
ARTERIOSCLEROSIS—PREVENTION AND CONTROL
Kuehl K. Preventive cardiology. 473.
ARTERIOVENOUS MALFORMATIONS-ETIOLOGY
Rubin JD; Ferencz C; McCarter RJ; Wilson PD; Boughman JA; Brenner JI; Neill CA; Perry LW; Hepner SI; Downing JW. Congenital cardiovascular malformations in the Baltimore-Washington area. 1079.
ARTHRODESIS
Lennox DW. Osteoarthritis VIII: Surgical management of the knee. 463.
ASTHMA
Petty VD. A medication record for asthmatics. 274.
Auxiliary see Medical and Chirurgical Faculty. Auxiliary

BACKACHE—THERAPY
Kolodny AL; Tendler J. Osteoarthritis XII: Management of low back pain. 1093.
Baeck ML; Eisenberg M. Carcinogenic risk assessment: Concepts and issues. 672.
Baltimore Center of the Systolic Hypertension in the Elderly Program (SHEP).
Entwisle G; Lewis C. Baltimore awarded a clinical center for the study of systolic hypertension in the elderly. 347.
Baltimore City Medical Society. Column. 1158.
Baltimore County Medical Association. Column. 334, 440.
Banta DA. On physicians' dispensing drugs. [letter]. 1087.
Baramki TA. see Waurin JL.
Baum RA. Esophageal varices. [editorial]. 357.
Bearman S. Members in the news. 1209.
Berger R. Cost analysis of AIDS cases in Maryland. 1173. see also Bland SM.
Berman MA. see Brenner JI.
BIOFEEDBACK (PSYCHOLOGY)
Research at the National Institute on Aging in behavioral training for high blood pressure control. 250.
BLACKS
Saunders E. Treatment of hypertension in special populations. 454.
Bland SM; Randy B; Flynn JPG; Kessler II. Characteristics of hospitalized TB patients: Montebello Center, Maryland, 1981 to 1983. 259.
Blass DA. Members in the news. 1209.
BLOOD DONORS
Maryland. Office of Disease Control and Epidemiology. Newsletter. 853.
BLOOD PRESSURE DETERMINATION
Lewis C. Historical notes: Early measurement of blood pressure 640.
Historical notes: Measurement of blood pressure II. 869.
Lewis C; Russell RP. Ambulatory blood pressure monitoring. 1057.
Russell RP; Lewis C. Ambulatory blood pressure monitoring: limitations and clinical uses. 1154.
BODY WEIGHT
Dimperio DL; Mahan CS. Influencing pregnancy outcome through nutrition and dietary changes. 997.
BONE DISEASES—REHABILITATION
Rosen NB; Sharoff K; Khanna V. Rehabilitation medicine. The dysfunctional pain patient—returning to work: a preliminary report. 605.
BOOK REVIEWS
Fedder DO; Russell RP. Second edition: *Management of essential hypertension*—a review. 552.
McGibbon BM. *Atlas of breast reconstruction following mastectomy* 114.
Twerski AJ. *It happens to doctors, too.* 1059.
Bormel P. Members in the news. 190.
Boughman JA. see Rubin JD.
Bowen BJ. see Sherman JL.
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BREAST DISEASE—PREVENTION & CONTROL
Elias EG. Breast masses: Screening and management. 642.
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Elias EG. The Management of primary carcinoma of the breast. 860.
Greenwald P. Diet and cancer prevention. 44.
Young Jr. JL; Horm JW. Cancer statistics in Maryland and the United States. 72.
Brenner JI; Ringel RE; Berman MA. Chest pain in children: identifying a source. 481.
see also Rubin JD.
Breschi L. Members in the news. 1209.
Briggs CM. The open forum. [letter]. 336.
Brown RC. see Beck GH.
Burnett JW; Elias EG. Screening and early detection of cutaneous melanoma. 442.

BURNS—DIAGNOSIS
Goans RE. Quantitative assessment of burn wound progress. 576.

Campbell JL; Valente CM; Levine D; Antlitz AM. Using four simple steps, physicians do influence smoking behavior. 50.
see also Valente CM.
CARCINOGENS, ENVIRONMENTAL—ANALYSIS
Baeck ML; Eisenberg M. Carcinogenic risk assessment: Concepts and issues. 672.
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Mix LA. A caricaturist's view of French physicians. 1103.
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The workings of the Physician-Patient Relations Committee. 436.
CARDIOVASCULAR SYSTEM-DRUG EFFECTS
Antidepressants and the cardiovascular system. 1061.
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Kuehl K. Preventive cardiology. 473.
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Ziminski CM. Osteoarthritis X: Cervical spondylosis. 683.
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Shubin CI. Child abuse and neglect: sexual abuse of prepubertal children. 503.
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de Bittner MR; Iber F. The use and abuse of cimetidine in a gastroenterology clinic. 359.
Citrin CM. see Sherman JL.
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COLONIC NEOPLASMS
Elias, EG. Management of primary adenocarcinoma of the large bowel. 349.
Greenwald P. Diet and cancer prevention. 44.
Tager AM; Sondik EJ. Economic evaluation of the benefits of cancer prevention and health promotion programs. 77.
Young JL; Horm JW. Cancer statistics in Maryland and the United States. 72.
COMMUNICABLE DISEASES
Flynn JPG. Reporting revisited [editorial]. 1167.
Gross TP; Lazar CP; Isreal E. The viral hepatitis surveillance system in the state of Maryland. 1169.
COMPUTERS
AMA's Survey and Opinion Briefs. Computer use among physicians. 735.
Szczepaniak A. Computerized literature searches. 556.
Do it yourself MEDLINE. 863.
Faculty begins access to AMA's medical information network. 246.
Cook DM. Members in the news. 190.
CONTRAST MEDIA—ADVERSE EFFECTS
Mueller PG. Emergency treatment of anaphylactoid reactions to radiographic contrast materials. 277.
CORNEA—TRANSPLANTATION
Susel RM. Corneal transplant donation. 588.
CORONARY DISEASE
Kuehl K. Preventive cardiology. 473.
Sherwin R; Lewis C. Effects of antihypertensive agents on lipids, lipoproteins, and coronary heart disease. 142.
COSTS AND COST ANALYSIS
Berger R. Cost analysis of AIDS cases in Maryland. 1173.
Meyerhoff J. Health care costs—past, present, and future. 167.
Covi L. Can suicide be predicted? 1139.
Covi L. What to treat: Anxiety or depression? 859.
Cox DS; VanSant KC. Resources: Cancer Prevention. 83.
Crenshaw C. Members in the news. 851.
CRIME—HISTORY
Howell NH. Dr. Samuel A. Mudd: Physician or traitor? 244.

Dans PE; Nevin KL. CPR: A Survey of Maryland hospitals. 1073.
Davis, Jr. FW. The many faces of apical hypertrophic cardiomyopathy. 1084.
de Bittner MR; Iber F. The use and abuse of cimetidine in a gastroenterology clinic. 359.
DeForge BR. see Valente CM.
DeLawter DE. see One Minute with Diabetes. Column.
DELIVERY
Nagey DA; Zachary A. Preterm delivery and patient education. 1006.
DEPRESSION
Antidepressants and the cardiovascular system. 1061.
Covi L. What to treat: Anxiety or depression? 859.
DeVita VJ. Cancer as a Preventable Disease. 41.
DIABETES MELLITUS
One minute with diabetes, 249, 350, 569, 873.
DIABETES MELLITUS, INSULIN-DEPENDENT
One minute with diabetes. 145, 440, 1060.
DIET
Dimperio DL; Mahan CS. Influencing pregnancy outcome through nutrition and dietary changes. 997.
Dimperio DL; Mahan CS. Influencing pregnancy outcome through nutrition and dietary changes. 997.
DIPHTHERIA TOXOID
Maryland. Office of Disease Control and Epidemiology. Newsletter. 33–34, 444–48.
DISCIPLINE COMMISSION ACTION. Column. 180, 514, 703, 917, 1116.
DISEASE—TRANSMISSION
Knapp VJ. The miasmatic and microscopic explanations for disease in the European past. 583.
Doctors Take Note. Column. 95, 194, 302, 407, 518, 614, 708, 817, 925, 1015, 1122, 1210.
Doman DB. Endoscopic sclerotherapy of esophageal varices. 355.
Dowling JW. see Rubin JD.
Drinkard, James Donald.
Med-Chi's 125th President: J.D. Drinkard MD. 757.
DRUG THERAPY
Elias EG. New drug development program. 1157.

EDUCATION, MEDICAL
Reed JW. Curriculum in ambulatory care. 281.
EDUCATION, MEDICAL, CONTINUING
Tanner TB. Dial Access: Call-in continuing medical education. 1101.
Eisenberg M. see Baeck ML.
ELECTROCARDIOGRAPHY
Brenner JI; Ringel RE; Berman MA. Chest pain in children: identifying a source. 481.
Davis, Jr FW. The many faces of apical hypertrophic cardiomyopathy. 1084.
Perry LW. Noninvasive assessment of pediatric congenital heart disease. 493.
Elias EG. Management of primary adenocarcinoma of the large bowel. 349.
The management of primary carcinoma of the breast. 860.
New drug development program. 1157.
Prognosis and management of cutaneous melanoma. 555.
Screening and early detection for adenocarcinoma of the large bowel. 248.
see also Burnett JW.
EMERGENCY MEDICAL SERVICES
Clemmens RL. Cardiac arrest: It happened to me. 1076.
EMPLOYMENT
Rosen NB; Sharoff K; Khanna V. Rehabilitation medicine. The dysfunctional pain patient—returning to work: a preliminary report. 605.
Entwisle G; Lewis C. Baltimore awarded a clinical center for the study of systolic hypertension in the elderly. 347.
ENVIRONMENTAL EXPOSURE—ANALYSIS
Baeck ML; Eisenberg M. Carcinogenic risk assessment: Concepts and issues. 672.
EQUIPMENT SAFETY
McClinton MA; Wright S. High-pressure tool injection injuries. 289.
Epperson-Sebour MM; Rifkin EW. Center for living: Trauma aftercare and outcome. 1187.
ESOPHAGEAL AND GASTRIC VARICES—THERAPY
Baum RA. Esophageal varices. [editorial]. 357.
Doman DB. Endoscopic sclerotherapy of esophageal varices. 355.
ESTROGENS
Schlaff WB; Rosenshein NB. Estrogens and endometrial cancer. 57.
EXHIBITS
Woolverton DK; Mix LA. "Toast them, burn them, roast them"
Ultraviolet ray therapy: The panacea of the 1920s and 1930s. 659.
Executive Director's Newsletter see Medical and Chirurgical Faculty. Executive Director's Newsletter.

EYE BANKS
Susel RM. Corneal transplant donation. 588.

FACILITY DESIGN AND CONSTRUCTION
Jensen JE. Your faculty library's place in the expanding faculty facilities. 438.
Building for 100 years—75 years ago. 668.
FEE SCHEDULES
O'Herlihy HT. Commission on Medical Discipline: dual fee schedule opinion. 461.
Feldman PR. Smoking and healthy pregnancy: Now is the time to quit. 982.
Ferencz C. see Rubin JD.
FETAL ALCOHOL SYNDROME
Mullins CL; Gazaway, III PM. Alcohol and drug use in pregnancy: A case for management. 991.
FETUS
Feldman PR. Smoking and healthy pregnancy: Now is the time to quit. 982.
Fishel ER. Members in the news. 190.
Flynn JPG. Reporting revisited. [editorial]. 1167.
Supervision of the impaired physician in a clinical practice setting. 161.
see also Bland SM.

Garg PP. see Heldrich FJ.
GASTROESOPHAGEAL REFLUX
Nasrallah SM. Use of 24-hour pH monitoring for gastroesophageal reflux. 571.
GASTROINTESTINAL DISEASES—THERAPY
de Bittner MR; Iber F. The use and abuse of cimetidine in a gastroenterology clinic. 359.
Gazaway III PM. see Mullins CL.
GENETIC MARKER
Waurin JL; Adams JE; Baramki TA. Prenatal Diagnosis of 45, X/46, XY. 883.
GLUCOSE TOLERANCE TEST—ADMINISTRATION AND USE
One minute with diabetes. Column. 662.
GLYCOSURIA
One minute with diabetes. 350.
Goans RE. Quantitative assessment of burn wound progress. 576.
Greenwald P. Diet and Cancer Prevention. 44.
Gross TP; Lazar CP; Isreal E. The viral hepatitis surveillance system in the state of Maryland. 1169.
Guandolo VL. Atypical Lyme Disease or Forme fruste. 687.

Haller LH. Members in the news. 851.
Harman SE. The biology of music making. 128.
see also Selected Medical Literature Searches.
HBP commentary. 142, 250, 347, 454, 552, 640, 869, 1057, 1154.
HEAD INJURIES
Epperson-Sebour MM; Rifkin EW. Center for living: Trauma aftercare and outcome. 1187.
Ranseen JD. Comprehensive rehabilitation of head injured adults. 1176.
HEALTH CARE OF THE ELDERLY
Stevens MB. Osteoarthritis VII: Rheumatic disease in the elderly. 367.
HEALTH MAINTENANCE ORGANIZATIONS
Meyerhoff J. Health care costs—past, present, and future. 167.
HEALTH PROMOTION
Tager AM; Sondik EJ. Economic evaluation of the benefits of cancer prevention and health promotion programs. 77.
HEALTH SERVICES FOR THE AGED
AMA's Survey and Opinion Briefs. The elderly and medical care in America: their own evaluation of quality, access, and cost. 598.
Entwisle G; Lewis C. Baltimore awarded a clinical center for the study of systolic hypertension in the elderly. 347.
HEALTH SURVEY
The AMA Map service. [Medical Miscellany]. 1086.
Dans PE; Nevin KL. CPR: A Survey of Maryland hospitals. 1073.
Valente CM; Sobal J; Muncie, Jr. HL; Levine DM; Antlitz AM; Deforge BR. Behavioral risks and pregnancy outcome: Attitudes and practices of OB/GYNS. 1003.
Rubin JD; Ferencz C; McCarter RJ; Wilson PD; Boughman JA; Brenner JI; Neill CA; Perry LW; Hepner SI; Downing JW. Congenital cardiovascular malformations in the Baltimore-Washington area. 1079.
HEART ARREST
Clemmens RL. Cardiac arrest: It happened to me. 1076.
HEART DEFECTS, CONGENITAL
Brenner JI; Ringel RE; Berman MA. Chest pain in children: identifying a source. 481.
Kidd L. Aftermath of pediatric heart surgery. 499.
Perry LW. The newborn with acyanotic congenital heart disease: recognition and management. 477.
Perry LW. Noninvasive assessment of pediatric congenital heart disease. 493.
Rubin JD; Ferencz C; McCarter RJ; Wilson PD; Boughman JA; Brenner JI; Neill CA; Perry LW; Hepner SI; Downing JW. Congenital cardiovascular malformations in the Baltimore-Washington area. 1079.
HEART DISEASES—DIAGNOSIS
Brenner JI; Ringel RE; Berman MA. Chest pain in children: identifying a source. 481.
HEART FAILURE, CONGESTIVE
Perry LW. The newborn with acyanotic congenital heart disease: recognition and management. 477.
Heldrich FJ; Garg PP. Occult hemorrhage in a neonate with hemophilia A. 351.
HEMATURIA
Alhasmimi MM; Krasnow SH. Hematuria from metastatic cancer to the kidney: case report and literature review. 595.
HEMOPHILIA—IN INFANCY AND CHILDHOOD
Heldrich FJ; Garg PP. Occult hemorrhage in a neonate with hemophilia A. 351.
HEMORRHAGE
Doman DB. Endoscopic sclerotherapy of esophageal varices. 355.
Heldrich FJ; Garg PP. Occult hemorrhage in a neonate with hemophilia A. 351.
HEPATITIS B
Maryland Office of Disease Control and Epidemiology. Newsletter. 339.
HEPATITIS VIRUSES
Gross TP; Lazar CP; Israel E. The viral hepatitis surveillance system in the state of Maryland. 1169.
Hepner SI. see Rubin JD.
Heuman P. Members in the news. 376.
Hill CD. Members in the news. 460.
HIP JOINT
Lennox DW. Osteoarthritis VI: The hip—surgical management. 267.
HISTORY OF MEDICINE
Knapp VJ. The miasmatic and microscopic explanations for disease in the European past. 583.
Hookman P. Members in the news. 376.
Horm JW. see Young JL.
HOSPITALS
Dans PE; Nevin KL. CPR: A Survey of Maryland hospitals. 1073.
Howell NH. Dr. Samuel A. Mudd: Physician or traitor? 244.
HUMAN T-CELL LEUKEMIA VIRUS
Maryland. Office of Disease Control and Epidemiology. Newsletter. 133, 563, 853.
HYPERTENSION
Entwisle G; Lewis G. Baltimore awarded a clinical center for the study of systolic hypertension in the elderly. 347.
Lewis C; Russell RP. Ambulatory blood pressure monitoring. 1057.
Research at the National Institute on Aging in behavioral training for high blood pressure control. 250.
Russell RP; Lewis C. Ambulatory blood pressure monitoring: limitations and clinical uses. 1154.
Saunders E. Treatment of hypertension in special populations. 454.
HYPOGLYCEMIA
One minute with diabetes. 350, 440.

Iber F. see de Bittner MR.
IDIOPATHIC HYPERTROPHIC SUBVALVULAR STENOSIS
Davis, Jr. FW. The many faces of apical hypertrophic cardiomyopathy. 1084.
IMMUNIZATION
Maryland. Office of Disease Control and Epidemiology. Newsletter. 223.
The Impaired Physician. [column]. 558, 663, 1059, 1136.
INCEST
Shubin CI. Child abuse and neglect: sexual abuse of prepubertal children. 503.

INFORMATION SYSTEMS—MARYLAND
Jensen JE. MARYLAND MED-SIG: A computer bulletin board for Maryland physicians. 338.
Inside Med-Chi. Column. 175, 241, 372, 436, 668, 877.
INSULIN
One minute with diabetes. 145.
Insurance Monitor. Column. 647, 874, 1088, 1162.
INTERVIEWS
Med-Chi's 125th President: J.D. Drinkard MD. 757.
INTESTINAL NEOPLASMS—PREVENTION AND CONTROL
Elias EG. Screening and early detection for adenocarcinoma of the large bowel. 248.
Israel E. see Gross TP.

Jensen JE.
Building for 100 years—75 years ago. 668.
MARYLAND MED-SIG: A computer bulletin board for Maryland physicians. 338.
Med-Chi's diligent ghost. 241.
Your Faculty Library's place in the expanding faculty facilities. 438.

Kasper R. Members in the news.
Katz RD. Recent advances in the early diagnosis of osteoporosis: A review. 889.
Keefe AT. Members in the news. 460.
Kessler, II. see Bland, SM.
Khanna V. see Rosen NB.
Kidd L. Aftermath of pediatric heart surgery. 499.
KIDNEY NEOPLASMS—SECONDARY
Alhasmimi MM; Krasnow SH. Hematuria from metastatic cancer to the kidney: case report and literature review. 595.
King AD. see Members in the News. 701.
Kirby RL. The open forum. [letter]. 335.
Knapp VJ. The miasmatic and microscopic explanations for disease in the European past. 583.
KNEE INJURIES—SURGERY
Lennox DW. Osteoarthritis VIII: Surgical management of the knee. 463.
KNEE PROTHESIS
Lennox DW. Osteoarthritis VIII: Surgical management of the knee. 463.
Kolodny AL; Tendler J. Osteoarthritis XII: Management of low back pain. 1093.
Konits PH. Members in the news. 190.
Krasnow SH. see Alhasmimi MM.
Kuehl K. Preventive cardiology. 473.

Lazar CP. see Gross TP.
Lehman E. Supporting Maryland physicians: The Med-Chi staff. 900.
Lennox DW. Osteoarthritis VI: The hip—surgical management. 267.
Osteoarthritis VIII: Surgical management of the knee. 463.
Levin ML. Miliary tuberculosis masquerading as late infection in total hip replacement. 153.
Levin N. Current approach to PID. 163.
Levine D. see Campbell JL.
Levine DM. see Valente CM.
Levitan L. Dear health care provider. [letter]. 743.
Lewis C. Historical notes: Measurement of blood pressure II. 869.
Historical notes: Early measurement of blood pressure. 640.
Russell RP. Ambulatory blood pressure monitoring. 1057.
see also Entwisle G.
see also Russell RP.
see also Sherwin R.
LIBRARIES, MEDICAL
Jensen JE. Your Faculty library's place in the expanding faculty facilities. 438.
Library Page. Column. 114, 128, 246, 338, 438, 659, 863, 1103, 1161.
LIFE STYLE
Raff BS. "Life-style" factors and pregnancy outcome. 975.
LIPIDS
Sherwin R; Lewis C. Effects of antihypertensive agents on lipids, lipoproteins, and coronary heart disease. 142.
LIPOPROTEINS
Sherwin R; Lewis C. Effects of antihypertensive agents on lipids, lipoproteins, and coronary heart disease. 142.
LUMBAR VERTEBRAE
Fine IT. Osteoarthritis XI: Lumbar spondylosis. 879.
Kolodny AL; Tendler J. Osteoarthritis XII: Management of low back pain. 1093.
LUNG NEOPLASMS
Alhasmimi MM; Krasnow SH. Hematuria from metastatic cancer to the kidney: case report and literature review. 595.
Young Jr JL; Horm JW. Cancer statistics in Maryland and the United States. 72.
Tager AM; Sondik EJ. Economic evaluation of the benefits of cancer prevention and health promotion programs. 77.
LYME DISEASE
Guandolo VL. Atypical Lyme disease or forme fruste. 687.
Maryland. Office of Disease Control and Epidemiology. Newsletter. 444.
Mensch J. Lyme Disease 691.

Mahan CS. see Dimperio DL.
MALARIA—PREVENTION AND CONTROL
Maryland. Office of Disease Control and Epidemiology. Newsletter. 651.
Malouf GS. Remarks at the Presidential Banquet. 761.
MALPRACTICE—LEGISLATION & JURISPRUDENCE
AMA's Survey and Opinion Briefs. Public support for malpractice reform. 255.
March of Dimes
Raff DS. Resources available from the March of Dimes. 1003.
Martinzo J. see Members in the News. 701.
Maryland. Commission on Hereditary disorders. Guidelines: screening for neural tube defects in the fetus. 586.
Maryland. Commission on Medical Discipline. see O'Herlihy HT.
Maryland. Office of Disease Control and Epidemiology. Newsletter. 31, 133, 223, 339, 445, 563, 651, 745, 853, 955, 1063, 1149.
Maryland High Blood Pressure Commission see HBP Commentary. Column.
Maryland MED-SIG
Jensen JE. MARYLAND MED-SIG: A computer bulletin board for Maryland physicians. 338.
Maryland Oncology Newsletter. 248, 349, 442, 555, 642, 860, 1055, 1157.
McCarter RJ. see Rubin JD.
McClinton MA; Wright S. High-pressure tool injection injuries. 289.
Medical and Chirurgical Faculty.
Ad Hoc Building Committee. 1984 Annual Report to the House of Delegates. 776.
Alcoholism Committee. 1984 Annual Report to the House of Delegates, 776.
American Medical Association Education and Research Foundation. 1984 Annual Report of the House of Delegates. 777.
Annual Reports of Committees Index. 762.
Auxiliary. Column. 175, 244, 374, 459, 553, 1102, 1138. 1984 Annual Report of the House of Delegates. 777.
Bylaws Committee. 1984 Annual Report to the House of Delegates. 778.
Committee on Drugs. 1984 Annual Report to the House of Delegates. 783.
Continuing Medical Education Review Committee. 1984 Annual Report to the House of Delegates. 778.
Council. 1984 Annual Report to the House of Delegates. 779.
Curator. 1984 Annual Report to the House of Delegates. 780.
Delegates to the AMA House of Delegates. 1984 Annual Report to the House of Delegates. 780.
Emergency Medical Services Committee. 1984 Annual Report to the House of Delegates. 783.
Emotional Heatlh Committee. 1984 Annual Report to the House of Delegates. 784.
Executive Director's Newsletter. 17, 119, 219, 325, 431, 541, 637, 731, 847, 949, 1051, 1145.
1984 Annual Report to the House of Delegates. 784.
Finance Committtee. 1984 Annual Report to the House of Delegates. 784.
Finney Fund Committee. 1984 Annual Report to the House of Delegates. 785.
Health Manpower and Planning Committee. 1984 Annual Report to the House of Delegates. 785.
House of Delegates. (314th Meeting) (187th Annual Session) April 25, 1985. Minutes. 763.
(315th Meeting) (187th Annual Session) April 27, 1985. Minutes. 773.
(316th Meeting) September 28, 1985. Minutes.
Hospital Medical Staffs Committee. 1984 Annual Report to the

House of Delegates. 785.
Insurance Fund. 1984 Annual Report to the House of Delegates. 794.
Legislative Committee. 1984 Annual Report to the House of Delegates. 786.
Liaison Committee with the Department of Health and Mental Hygiene. 1984 Annual Report to the House of Delegates. 788.
Liaison with Third Party Carriers Committee. 1984 Annual Report to the House of Delegates. 788.
Library and History Committee. 1984 Annual Report to the House of Delegates. 791.
Long Term Care and Geriatrics Committee. 1984 Annual Report to the House of Delegates. 793.
Maryland Medical Journal. 1984 Annual Report to the House of Delegates. 794.
Medicine and Religion Committee. 1984 Annual Report to the House of Delegates. 795.
Medicolegal Committee. 1984 Annual Report to the House of Delegates. 795.
Nominating Committee. 1984 Annual Report to the House of Delegates. 796.
Occupational Health Committee. 1984 Annual Report to the House of Delegates. 797.
Peer Review Committee. 1984 Annual Report to the House of Delegates. 797.
Physician/Patient Relations Committee. 1984 Annual Report to the House of Delegates. 798.
Physician Rehabilitation Committee. 1984 Annual Report to the House of Delegates. 799.
Preventive Medicine and Public Health. 1984 Annual Report to the House of Delegates. 800.
Professional Ethics Committee. 1984 Annual Report to the House of Delegates. 801.
Public Relationships Committee. 1984 Annual Report to the House of Delegates. 801.
Reference Committee. 1984 Annual Report to the House of Delegates. 802.
Scientific Activity Committee. 1984 Annual Report to the House of Delegates. 803.
Secretary. 1984 Annual Report to the House of Delegates. 805.
Tel-Med Committee. 1984 Annual Report to the House of Delegates. 805.
Treasurer. 1984 Annual Report to the House of Delegates. 807.

MEDICAL ONCOLOGY
Elias, EG. Management of primary adenocarcinoma of the large bowel. 349.

MEDICAL RECORDS
Petty VD. A medication record for asthmatics. 274.

MELANOMA
Burnett JW; Elias EG. Screening and early detection of cutaneous melanoma. 442.
Elias EG. Cutaneous melanoma: Differential diagnosis. 1055. Prognosis and management of cutaneous melanoma. 555.

Members in the News. Column. 190, 376, 460, 701, 851, 1209.
Mensch J. Lyme Disease. 691.
Meyerhoff J. Health care costs—past, present, and future. 167.
Millicovsky LJ. Members in the news. 460.

MINET (AMA/GTE Medical Information Network).
Szczepaniak A. Faculty begins access to AMA's medical information network. 241.

Mix LA. A caricaturist's view of French physicians. 1103.
see also Woolverton DK.

MONITORING, PHYSIOLOGIC
Nasrallah SM. Use of 24-hour pH monitoring for gastroesophageal reflux. 571.

Montebello Center, Maryland.
Bland SM; Randy B; Flynn JPG; Kessler II. Characteristics of hospitalized TB patients: Montebello Center, Maryland, 1981 to 1983. 259.

MOTIVATION
Boyd MD. Patient motivation during pregnancy. 977.

Morrison S. Changing patterns [letter]. 551.

Mudd, Samuel A.
Howell, NH. Dr. Samuel A. Mudd: Physician or traitor? 244.

Mueller PG. Emergency treatment of anaphylactoid reactions to radiographic contrast materials. 277.
Mullins CL; Gazaway, III PM. Alcohol and drug use in pregnancy: A case for management. 991.
Muncie HL. see Valente CM.
Munoz P. 1986 periodicals. 1161.

MUSCULAR DISEASES—REHABILITATION
Rosen NB; Sharoff K; Khanna V. Rehabilitation medicine. The dysfunctional pain patient—returning to work: a preliminary report. 605.

MUSIC
Harman SE. The biology of music making. 128.

Nagey DA; Zachary A. Preterm delivery and patient education. 1006.
Nakazawa H. Members in the news. 190.
Nasrallah SM. Use of 24-hour pH monitoring for gastroesophageal reflux. 571.
Navarro AH; Sutton JD. Osteoarthritis IX: biochemical factors, prevention, and nonpharmacologic management. 591.
Navarro AH; Sutton JD. Osteoarthritis IX: biochemical factors, prevention, and nonpharmacologic management. 591.
Neill CA. see Rubin JD.

NEOPLASMS
DeVita VJ. Cancer as a preventable disease. 41.
Greenwald P. Diet and Cancer Prevention. 44.
Schlaff WB; Rosenshein NB. Estrogens and endometrial cancer. 57.
Tager AM; Sondik EJ. Economic evaluation of the benefits of cancer prevention and health promotion programs. 77.
Young Jr JL; Horm JW. Cancer statistics in Maryland and the United States. 72.

NEURAL TUBE DEFECTS—DIAGNOSIS
Maryland. Commission on Hereditary disorders. Guidelines: screening for neural tube defects in the fetus. 586.

Nevin KL. see Dans PE.

Noyes, Marcia Crocker.
Jensen, JE. Med-Chi's diligent ghost. 241.

NUCLEAR MAGNETIC RESONANCE
Sherman JL; Citrin CM; Bowen BJ. Clinical magnetic resonance imaging. 679.

NUTRITION
Dimperio DL; Mahan CS. Influencing pregnancy outcome through nutrition and dietary changes. 997.

O'Herlihy HT. Commission on Medical Discipline: Dual fee schedule opinion. 461.

OBESITY IN DIABETES
One minute with diabetes. 249.

OBSTETRICS
Valente CM; Sobal J; Muncie, Jr. HL; Levine DM; Antlitz AM; Deforge BR. Behavioral risks and pregnancy outcome: Attitudes and practices of OB/GYNS. 1003.

One Minute With Diabetes. Column. 145, 249, 350, 440, 569, 662, 873, 1060, 1159.

ONLINE SYSTEMS—MARYLAND
Jensen JE. Maryland MED-SIG: A computer bulletin board for Maryland physicians. 338.
Szczepaniak A. Do it yourself Medline. 863.

The Open Forum. Column. 335, 1087.

OSTEOARTHRITIS
Fine IT. Osteoarthritis XI: Lumbar spondylosis. 879.
Kolodny AL; Tendler J. Osteoarthritis XII: Management of low back pain. 1093.
Lennox DW. Osteoarthritis VI: The hip—surgical management. 267.
Osteoarthritis VIII: Surgical management of the knee. 463.
Navarro AH; Sutton JD. Osteoarthritis IX: biochemical factors, prevention, and nonpharmacologic management. 591.
Ziminski CM. Osteoarthritis X: Cervical spondylosis. 683.
Zizic TM. Osteoarthritis V: Medical management. 147.

OSTEOPOROSIS
Katz RD. Recent advances in the early diagnosis of osteoporosis: A review 889.

OVARIAN NEOPLASMS—DIAGNOSIS
VillaSanta U. What a physician should know about ovarian cancer. 693.

PAIN
Brenner JI; Ringel RE; Berman MA. Chest pain in children: identifying a source. 481.
Rosen NB; Sharoff K; Khanna V. Rehabilitation medicine. The dysfunctional pain patient—returning to work: a preliminary report. 605.

PATIENT COMPLIANCE
Bland SM; Randy B; Flynn JPG; Kessler II. Characteristics of hospitalized TB patients: Montebello Center, Maryland, 1981 to 1983. 259.
PATIENT EDUCATION
AMA's Survey Opinion and Briefs. Patient education, PMIs, and physician opinion. 116.
Nagey DA; Zachary A. Preterm delivery and patient education. 1006.
Raff BS. Resources available from the March of Dimes. 1003.
PEER REVIEW—MARYLAND
Casey NC. The importance of medical peer review. 877.
PERCEPTION
Wilson J; Romano RM; Stein J. Public perception of cancer risk and prevention; Implications for physicians. 63.
PERIODICALS
Munoz P. 1986 periodicals. 1161.
Perry LW. The newborn with acyanotic congenital heart disease: recognition and management. 477.
Noninvasive assessment of pediatric congenital heart disease. 493.
see also Rubin JD.
PERTUSSIS VACCINE
Maryland. Office of Disease Control and Epidemiology. Newsletter. 33, 223, 444
Petty VD. A medication record for asthmatics. 274.
PHYSICAL THERAPY
Navarro AH; Sutton JD. Osteoarthritis IX: biochemical factors, prevention, and nonpharmacologic management. 591.
PHYSICIAN IMPAIRMENT
Flynn JPG. Supervision of the impaired physician in a clinical practice setting. 161.
Townsend CE. Committee on Physician Rehabilitation. 372.
Valaske MJ. What he doesn't know will hurt him. 558.
Nobody knows. 1136.
The target of our concern. 663.
PHYSICIAN-PATIENT RELATIONS
AMA's Survey Opinion and Briefs. Public image of physicians revisited. 875.
Campbell JL; Valente CM; Levine D; Antlitz AM. Using four simple steps, physicians do influence smoking behavior. 50.
Casey NC. The workings of the Physician-Patient Relations Committee. 436.
PHYSICIANS
AMA's Survey and Opinion Briefs. Computer use among physicians. 735.
Patient education, PMIs, and physician opinion. 116.
Mix LA. A caricaturist's view of French physicians. 1103.
Valente CM; Campbell JL. Cancer risk reduction: A focus on physicians. 67.
Valente CM; Sobal J; Muncie Jr HL; Levine DM; Antlitz AM; Deforge BR. Behavioral risks and pregnancy outcome: Attitudes and practices of OB/GYNS. 1003.
PHYSIOLOGY—HISTORY
Lewis C. Historical notes: Early measurement of blood pressure 640.
POSTOPERATIVE CARE
Kidd L. Aftermath of pediatric heart surgery. 499.
PREGNANCY
Dimperio DL; Mahan CS. Influencing pregnancy outcome through nutrition and dietary changes. 997.
PREGNANCY COMPLICATIONS
Nagey DA; Zachary A. Preterm delivery and patient education. 1006.
Raff BS. "Life-style" factors and pregnancy outcome. 975.
PRENATAL CARE
Boyd MD. Patient motivation during pregnancy. 977.
Feldman PR. Smoking and healthy pregnancy: Now is the time to quit. 982.
Mullins CL; Gazaway, III PM. Alcohol and drug use in pregnancy: A case for management. 991.
PRENATAL DIAGNOSIS
Maryland. Commission on Hereditary disorders. Guidelines: screening for neural tube defects in the fetus. 586.
PRENATAL EXPOSURE DELAYED EFFECTS
Feldman PR. Smoking and healthy pregnancy: Now is the time to quit. 982.
Mullins CL; Gazaway, III PM. Alcohol and drug use in pregnancy: A case for management. 991.
PREVENTIVE HEALTH SERVICES
Cox DS; VanSant KC. Resources: Cancer Prevention. 83.
PUBLIC HEALTH
Flynn JPG. Reporting revisited. [editorial]. 1167.
Gross TP; Lazar CP; Isreal E. The viral hepatitis surveillance system in the state of Maryland. 1169.
PUBLIC OPINION
AMA's Survey and Opinion Briefs. Public image of physicians revisited. 875.
Wilson J; Romano RM; Stein J. Public perception of cancer risk and prevention; Implications for physicians. 63.

RADIOGRAPHY
Perry LW. Noninvasive assessment of pediatric congenital heart disease. 493.
RADIONUCLIDE IMAGING.
Katz RD. Recent advances in the early diagnosis of osteoporosis: A review. 889.
Raff BS. "Life-style" factors and pregnancy outcome. 975.
Randy B. see Bland SM.
Ranseen JD. Comprehensive rehabilitation of head injured adults. 1176.
RAPE
Shubin CI. Child abuse and neglect: sexual abuse of prepubertal children. 503.
Rausch PG. The open forum. [letter]. 335.
Reed JW. Curriculum in ambulatory care. 281.
REHABILITATION CENTERS
Ranseen JD. Comprehensive rehabilitation of head injured adults. 1176.
Epperson-Sebour MM; Rifkin EW. Center for living: Trauma aftercare and outcome. 1187.
Reichel W. Members in the news. 1209.
Reichelderfer TE. Members in the news. 460.
REIMBURSEMENT MECHANISMS—TRENDS
AMA's Survey and Opinion Briefs. Physicians' preferences for payment methods. 377.
RELAXATION TECHNICS
Research at the National Institute on Aging in behavioral training for high blood pressure control. 250.
RESUSCITATION
Dans PE; Nevin KL. CPR: A survey of Maryland hospitals. 1073.
RHEUMATISM—COMPLICATIONS
Stevens MB. Osteoarthritis VII: Rheumatic disease in the elderly. 367.
Richards RD. Members in the news. 190.
Rifkin EW. see Epperson-Sebour MM.
Rinn WA. Members in the news. 190.
Ringel RE. see Brenner JI.
RISK
Feldman PR. Smoking and healthy pregnancy: Now is the time to quit. 982.
Raff BS. "Life-style" factors and pregnancy outcome. 975.
ROCKY MOUNTAIN SPOTTED FEVER
Maryland. Office of Disease Control and Epidemiology. Newsletter. 444.
Romano RM. see Wilson J.
Rosen NB; Sharoff K; Khanna V. Rehabilitation medicine. The dysfunctional pain patient—returning to work: a preliminary report. 605.
Rosenberg GL. Members in the news. 190.
Rosenshein NB. see Schlaff WB.
RUBELLA—ETIOLOGY
Maryland. Office of Disease Control and Epidemiology. Newsletter. 651.
Rubin JD; Ferencz C; McCarter RJ; Wilson PD; Boughman JA; Brenner JI; Neill CA; Perry LW; Hepner SI; Downing JW. Congenital cardiovascular malformations in the Baltimore-Washington area. 1079.
RUNNING
Clemmens RL. Cardiac arrest: It happened to me. 1076.
Russell RP; Lewis C. Ambulatory blood pressure monitoring: limitations and clinical uses. 1154.
see also Lewis C.

Sargeant J. see Medical and Chirurgical Faculty. Executive Director's Newsletter.

see also Your Medical Faculty at Work. Column.
Saunders E. Treatment of hypertension in special populations. 454.
Schlaff WB; Rosenshein NB. Estrogens and endometrial cancer. 57.
SCLEROSING SOLUTIONS
Baum. RA. Esophageal varices. [editorial]. 357.
SCLEROSING SOLUTIONS—ADMINISTRATION & DOSAGE
Doman DB. Endoscopic sclerotherapy of esophageal varices. 353.
Selected Medical Literature Searches. Column. 132, 247, 338, 439, 557, 661, 863, 1106, 1161.
SERODIAGNOSIS
Maryland. Office of Disease Control and Epidemiology. Newsletter 853.
Sharoff K. see Rosen NB.,
Sherman JL; Citrin CM; Bowen BJ. Clinical Magnetic Resonance Imaging. 679.
Sherwin R; Lewis C. Effects of antihypertensive agents on lipids, lipoproteins, and coronary heart disease. 142.
Shubin CI. Child abuse and neglect: sexual abuse of prepubertal children. 503.
SKIN NEOPLASMS
Burnett JW; Elias EG. Screening and early detection of cutaneous melanoma. 442.
Elias EG. Cutaneous melanoma: Different diagnosis. 1055. Prognosis and management of cutaneous melanoma. 555.
SMOKING
Boyd MD. Patient motivation during pregnancy. 977.
Brandt EN. Smoking: The number one health problem. 897.
Campbell JL; Valente CM; Levine D; Antlitz AM. Using four simple steps, physicians do influence smoking behavior. 50.
DeVita VJ. Cancer as a preventable disease. 41.
Feldman PR. Smoking and healthy pregnancy: Now is the time to quit. 982.
Sobal J. see Valente CM.
SOCIAL JUSTICE—HISTORY
Howell, NH. Dr. Samuel A. Mudd: Physician or traitor? 244.
SOCIETIES, MEDICAL
Casey NC. The importance of medical peer review. 877.
Jensen JE. Med-Chi's diligent ghost. 241.
Building for 100 years—75 years ago. 668.
Lehman E. Supporting Maryland physicians: The Med-Chi staff. 900.
Townsend CE. Committee on Physician Rehabilitation. 372.
Sondik EJ. see Tager AM.
Southern Medical Association
Tanner TB. Dial Access: Call-in continuing medical education. 1101.
Stein J. see Wilson J.
Stevens MB. Osteoarthritis VII: Rheumatic disease in the elderly. 367.
SUBSTANCE ABUSE
Mullins CL; Gazaway, III PM. Alcohol and drug use in pregnancy: A case for management. 991.
SUBSTANCE DEPENDENCE
Valaske MJ. What he doesn't know will hurt him. 558.
The target of our concern. 663.
SUICIDE
Covi L. Can suicide be predicted? 1139.
Sumner JA. Members in the news. 191, 851.
Susel RM. Corneal transplant donation. 588.
Sutton JD. see Navarro AH.
SWEETENING AGENTS
One minute with diabetes. 569.
Szczepaniak A. Computerized literature searches. 556.
Do it yourself MEDLINE. 863.
Faculty begins access to AMA's medical information. 246.

Tager AM; Sondik EJ. Economic evaluation of the benefits of cancer prevention and health promotion programs. 77.
Tanner TB. Dial Access: Call-in continuing medical education. 1101.
Taylor JE. Members in the news. 376.
Taylor M. The Auxiliary to Med-Chi—growth and expansion. 175.
TELEPHONE
Tanner TB. Dial Access: Call-in continuing medical education. 1101.
Tendler J. see Kolodny AL.
TETANUS TOXOID
Maryland. Office of Disease Control and Epidemiology. Newsletter. 33, 444.
THORAX
Brenner JI; Ringel RE; Berman MA. Chest pain in children: identifying a source. 481.
Today's Psychiatry. [column]. 859, 1061, 1139.
Townsend CE. Committee on Physician Rehabilitation. 372.
TOMOGRAPHY, X-RAY Computed.
Sherman JL; Citrin CM; Bowen BJ. Clinical magnetic resonance imaging. 679.
TUBERCULOSIS
Bland SM; Randy B; Flynn JPG; Kessler II. Characteristics of hospitalized TB patients: Montebello Center, Maryland 1981 to 1983. 259.
Levin ML. Military tuberculosis masquerading as late infection in total hip replacement. 153.
Turner CJ. The open forum. [letter]. 335.

ULTRASONICS—DIAGNOSTIC USE
Goans RE. Quantitative assessment of burn wound progress. 576.
ULTRAVIOLET THERAPY—HISTORY
Woolverton DL; Mix LA. "Toast them, burn them, roast them" Ultraviolet ray therapy: The panacea of the 1920s and 1930s. 659.
UTERINE NEOPLASMS
Schlaff WB; Rosenshein NB. Estrogens and endometrial cancer. 57.

Valaske MJ. Nobody knows. 1136.
The target of our concern. 663.
What he doesn't know will hurt him. 558.
Valente CM; Campbell JL. Cancer risk reduction: A focus on physicians. 67.
;Sobal J; Muncie, Jr. HL; Levine DM; Antlitz AM; Deforge BR. Behavioral risks and pregnancy outcome: Attitudes and practices of OB/GYNS. 1003.
see also Antlitz AM.
see also Campbell JL
VanSant KC. see Cox DS.
VENEREAL DISEASES—OCCURRENCE
Maryland. Office of Disease Control and Epidemiology. Newsletter. 955.
VillaSanta U. What a physician should know about ovarian cancer. 693.
VIRAL HEPATITIS VACCINES
Maryland. Office of Disease Control and Epidemiology. Newsletter. 31, 339.
VIREMIA
Maryland. Office of Disease Control and Epidemiology. Newsletter. 563.
VITAMIN A
Greenwald P. Diet and cancer prevention. 44.

Waurin JL; Adams JE; Baramki TA. Prenatal diagnosis of 45, X/46, XY. 883.
WHOOPING COUGH
Maryland. Office of Disease Control and Epidemiology. Newsletter. 444.
Wilson J; Romano RM; Stein J. Public perception of cancer risk and prevention: Implications for physicians. 63.
Wilson PD. see Rubin JD.
Woolverton DK; Mix LA. "Toast them, burn them, roast them" Ultraviolet ray therapy: The panacea of the 1920s and 1930s. 659.
Wright RK. Members in the news. 191.
Wright S. see McClinton MA.

Yosuico JM. Members in the news. 190.
Young JL; Horm JW. Cancer statistics in Maryland and the United States. 72.
Your Medical Faculty at Work. Column. 11, 293, 334, 437, 570, 743, 1088, 1160.

Zachary A. see Nagey DA.
Zajano DP. see Members in the News. 701.
Ziminski CM. Osteoarthritis X: Cervical spondylosis. 683.
Zizic TM. Osteoarthritis V: Medical management. 147.

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Med-Chi 1137, 1209, 1213
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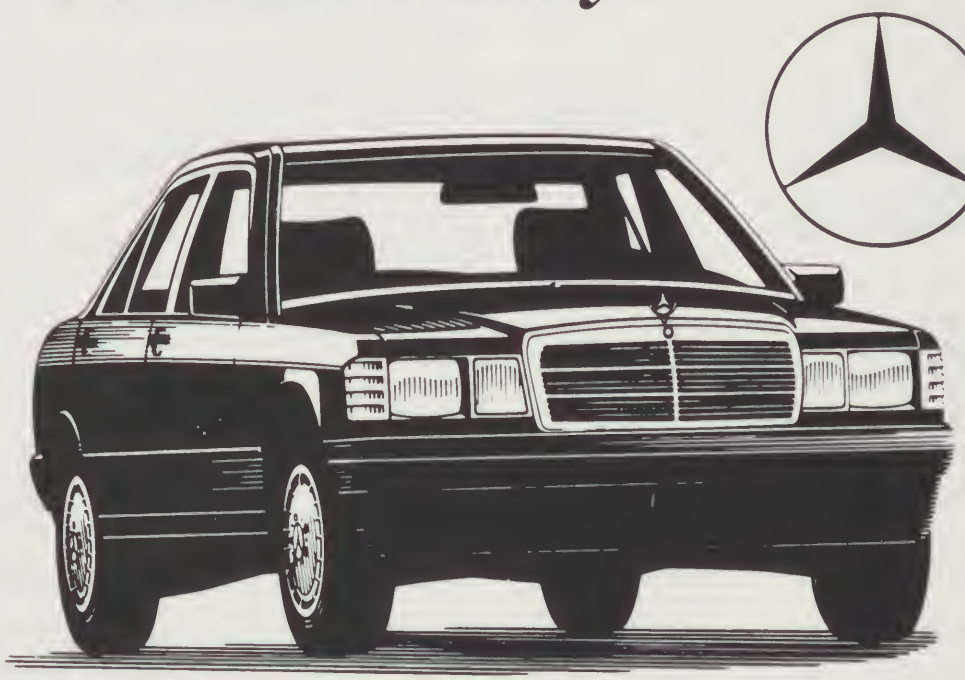
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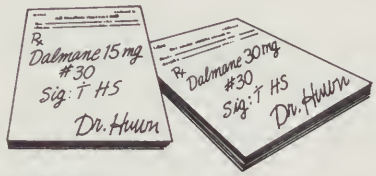
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